HOME PROTHROMBIN TIME MONITORS
DME101.038
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COVERAGE:

Prothrombin time home monitoring devices are considered medically necessary when used to regulate anti-coagulant therapy in selected high risk members, including:

- Patients with mechanical heart valves who have undergone anticoagulation management for at least three months; OR
- Patients requiring anticoagulation to similar levels as mechanical heart valve, i.e., an International Normalized Ratio (INR) of greater than 3.

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. Patients with mechanical heart valves are frequently anticoagulated at higher levels than anticoagulated 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 INR. For example, an INR >3 results in a higher risk of serious hemorrhage, while an INR of 6 increases the risk of developing a serious bleed nearly 7 times that of someone with INR below 3. In contrast, an INR below 2 is associated with increased risk of stroke. Therefore, monitoring of the prothrombin times 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 every 2-3 weeks; or
- Home prothrombin time monitors (<5%).

There are several different devices approved by the U. S. Food and Drug Administration (FDA) that may be purchased by the patient for in-home monitoring of chronic anti-coagulant therapy. The FDA approval for all of these devices was based on the demonstration that appropriately trained patients could generate INR test results comparable to laboratory measures. However, 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:

- Increasing the time that the anticoagulation is within a therapeutic INR range (intermediate health outcome); and

- 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 in the results of the self-monitoring and receive further telephonic instructions on warfarin dose.

RATIONALE:

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 was typically associated with more intense monitoring. Final health outcomes would ideally focus on the incidence of hemorrhagic or embolic events. However, due to the low incidence of the events, published studies have primarily focused on the intermediate outcomes of time spent in the therapeutic rate of warfarin, as measured by the 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 an increase in the PT “time in therapeutic range” (TTR) from 6% to 34%. 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 self-monitoring and management group or the usual care group. The self-monitoring group receive 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%). After 6 months, there was no difference in the frequency of major bleeding between the 2 groups. The time in the therapeutic range also
increased in the self-monitoring group, from 32% in the usual care group to 56% in the self-monitoring group.

The Early Self Controlled Anticoagulation Trial (ESCAT) is a trial of 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. The authors evaluated complication on a 4-grade scale. For example, grad III was defined as a complication requiring hospitalization. In the treatment group, 9.5% required hospitalization compared to the 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 anticoagulated at higher levels, this subset of patients are more likely to benefit from self-monitoring and management.

PRICING:

None

REFERENCES:


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HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.