I. 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.

II. 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 anticoagulant 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). The target INR range is 2.0 to 3.0 for most patients. An INR result greater than 3 indicates an increased risk of serious hemorrhage, while an INR less than 2 is associated with an increased risk of stroke. An INR of 6 indicates an increased risk of developing a serious bleed nearly 7 times that of someone with an INR less than 3. 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: 1) in the physician's office (usually once a month), at an anticoagulation clinic (usually once every 2 to 3 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.

III. Criteria/Guidelines

A. At-home monitoring of chronic warfarin therapy may be considered 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. Before initiation of at-home monitoring, patients must have undergone anticoagulation management for at least 3 months.

B. Home INR is covered when a patient meets one of the following:
   1. Has limited or no access to a lab
   2. Has chronically unstable INR
   3. Has a doctor certify that the patient is homebound. Homebound is defined as:
      a. Leaving home is not recommended because of the patient’s condition
      b. Patient’s condition keeps him from leaving home without help (such as a wheelchair or walker, needing special transportation, or getting help from another person).
      c. Leaving home takes a considerable and taxing effort

C. 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.

D. The Home INR device must be U.S. Food and Drug Administration (FDA) approved.

IV. Limitations

A. Additional hardware/software systems needed for down-loading data from prothrombin time home testing units to computers for the management of anticoagulation is not covered.

B. Self-testing with the device should not occur more frequently than once a week.

V. Administrative Guidelines

A. Home INR supplies require precertification. Requests for precertification for Home INR must be accompanied by clinical documentation from the requesting physician. To precertify, please complete HMSA’s Pre-certification Request and mail or fax the form as indicated.

B. Covered codes:

<table>
<thead>
<tr>
<th>HCPC Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous (code to use when billing for monitor)</td>
</tr>
<tr>
<td>A9900</td>
<td>Miscellaneous DME supply, accessory, and/or service component of another HCPCS code (code to use when billing for strips)</td>
</tr>
</tbody>
</table>
A9999  Miscellaneous DME supply or accessory, not otherwise specified (code to use when billing for strips)

G0248  Demonstration, prior to initial use, 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 ability to perform testing prior to its use

VI. Important Reminder

The purpose of this Medical Policy is to provide a guide to coverage. This Medical Policy is not intended to dictate to providers how to practice medicine. Nothing in this Medical Policy is intended to discourage or prohibit providing other medical advice or treatment deemed appropriate by the treating physician.

Benefit determinations are subject to applicable member contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

This Medical Policy has been developed through consideration of the medical necessity criteria under Hawaii’s Patients’ Bill of Rights and Responsibilities Act (Hawaii Revised Statutes §432E-1.4), generally accepted standards of medical practice and review of medical literature and government approval status. HMSA has determined that services not covered under this Medical Policy will not be medically necessary under Hawaii law in most cases. If a treating physician disagrees with HMSA’s determination as to medical necessity in a given case, the physician may request that HMSA reconsider the application of the medical necessity criteria to the case at issue in light of any supporting documentation.

VII. References

5. Matchar DB, Jacobson AK, Edson RG 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


