I. Policy: Prothrombin Time Home Testing

II. Purpose/Objective:
To provide a policy of coverage regarding Prothrombin Time Home Testing

III. Responsibility:
A. Medical Directors
B. Medical Management

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community.
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) The service or benefit will assist the Member to achieve or maintain maximum functional
capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:
Home prothrombin time testing systems are portable, hand-held, battery operated devices designed to analyze fresh capillary blood samples obtained by finger-stick using a lancet device. Both prothrombin time (PT) and international normalized ratio (INR) are displayed to aid in the management of high-risk members who are taking oral anticoagulation medications.

INDICATIONS:
Home prothrombin time testing systems will be evaluated for clinical appropriateness for selected members who are considered to be high risk of thromboembolism because of illness severity, instability of anticoagulation levels, or other complicating factors, and who meet all of the following criteria:

- Member requires anticoagulation therapy due to a mechanical heart valve, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism); and
- Member requires long term (defined as greater than 6 months) oral anticoagulation therapy; and
- Member has been anticoagulated for a minimum of three months prior to the request for the home prothrombin time monitor; and
- Documentation has been submitted to show that the member has completed a face to face physician directed educational program on anticoagulation management and the use of the device, and has demonstrated the ability to use the device correctly.
- The member continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring.

LIMITATIONS:
Based on the supporting published clinical trials data, self-testing more frequently than once per week is not medically necessary.

CODING ASSOCIATED WITH: Home Prothrombin Time monitor
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

G0248 Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration 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 a patient ability to perform testing

G0249 Provision of test material and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests (does not require face-to-face service).

G0250 Physician review, interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face service).

ICD10 Codes
D68.51, D68.52, D68.59, D68.61, D68.62, I26.90, I26.99, I26.01, I26.09, I27.24, I48.0, I48.2, I80.01, I80.02, I80.03, I80.1, I80.12, I80.13, I80.201, I80.202, I80.203, I80.221, I80.222, I80.223, I80.231, I80.232, I80.233, I80.291, I80.292, I80.293, I80.211, I80.212, I80.213, I80.8, I82.0, I82.1, I82.220, I82.221, I82.3, I82.401, I82.402, I82.403, I82.411, I82.412, I82.413, I82.421, I82.422, I82.423, I82.431, I82.432, I82.433, I82.441, I82.442, I82.443, I82.491, I82.492, I82.493, I82.494, I82.4Z1, I82.4Z2, I82.4Z3, I82.501, I82.502, I82.503, I82.508, I82.509, I82.592, I82.593, I82.594, I82.511, I82.512, I82.513, I82.521, I82.522, I82.523, I82.531, I82.532, I82.533, I82.541, I82.542, I82.543, I82.5Z1, I82.5Z2, I82.5Z3, I82.811, I82.812, I82.813, I82.711, I82.712, I82.713, I82.721, I82.722, I82.723, I82.701, I82.702, I82.703, I82.704, I82.721, I82.722, I82.723, I82.701, I82.702, I82.703, I82.704, I82.721, I82.722, I82.723, I82.701, I82.702, I82.703, I82.704, I82.721, I82.722, I82.723, I82.701, I82.702, I82.703, I82.704, I82.811, I82.812, I82.813, I82.814, I82.815, I82.816, I82.817, I82.818, I82.819, I82.820, I82.821, I82.822, I82.823, I82.824, I82.825, I82.826, I82.827, I82.828, I82.829, I82.830, I82.831, I82.832, I82.833, I82.834, I82.835, I82.836, I82.837, I82.838, I82.839, I82.840, I82.841, I82.842, I82.843, I82.844, I82.845, I82.846, I82.847, I82.848, I82.849, I82.850, I82.851, I82.852, I82.853, I82.854, I82.855, I82.856, I82.857, I82.858, I82.859, I82.860, I82.861, I82.862, I82.863, I82.864, I82.865, I82.866, I82.867, I82.868, I82.869, I82.870, I82.871, I82.872, I82.873, I82.874, I82.875, I82.876, I82.877, I82.878, I82.879, I82.880, I82.881, I82.882, I82.883, I82.884, I82.885, I82.886, I82.887, I82.888, I82.889, I82.890, Z95.2, I23.6, I27.82, I67.6, O22.51, O22.52, O22.53, O87.3, Z79.01, Z86.718, Z95.4

LINE OF BUSINESS:
Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


Cromheeke ME, Levi M, Colly LP, et. al. Self management of long term oral anticoagulation was as effective as specialist anticoagulation clinic management. Evidence Based Medicine Mar/Apr 2001; 6:41.


This policy will be revised as necessary and reviewed no less than annually.

Devised: 10/20/05

Revised: 10/06, 11/10 (criteria); 6/15 (revised criteria), 10/17 (Removed Homebound List)

Reviewed: 11/07, 11/11, 11/12, 11/13, 11/14, 12/16, 10/18, 10/19