NorthEast Ohio Neighborhood Health Services, Inc ANTICOAGULATION CLINIC PROTOCOL

August 2012 Revision

Background:

It was determined that NEON does not have the capacity, at present, to safely distribute the principle management of anticoagulation therapy to individual NEON primary care providers at individual health centers at the various clinical units. It was concluded through trials and tribulation that management of anticoagulation must be delegated to a focus clinic (or a comparable clinic at a Joint Commission accredited facility) for all NEON patients prescribed maintenance Coumadin/Warfarin therapy for

Affirmation:

All Adult Medicine patients who are on anticoagulation therapy with Coumadin/Warfarin must have their anticoagulation needs managed with the direct participation of NEON's Anticoagulation Clinic or an alternative Anticoagulation Clinic that is operated by a Joint Commission accredited facility.

Objectives of NEON's Anticoagulation Clinic:

- 1. For patients receiving anticoagulation therapy, to improve their outcomes through patient education, effective periodic assessments, efficient monitoring of anticoagulation, and efficacious dosing of Coumadin/Warfarin.
- 2. To increase compliance with anticoagulation therapy.
- 3. To adhere to the Joint Commission's National Patient Safety Goal NPSG.03.05.01: "Reduce the likelihood of patient harm associated with the use of anticoagulant therapy; where this requirement applies to organizations that provide anticoagulant therapy and/or long-term anticoagulation prophylaxis (for example, atrial fibrillation) where the clinical expectation is that the patient's laboratory values for coagulation will remain outside normal values."

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*Revised

Responsibility of Primary Care Provider in relationship to NEON's Anticoagulation Clinic (NAC):

- 1. Order and prescribe a maintenance dose of Coumadin/Warfarin.
- 2. Specify in the EMR Anticoagulation Template the INR range and duration of therapy.
- 3. Specify in EMR Anticoagulation Template the medical condition that is the basis/reason for anticoagulation.
- 4. If possible, obtain and submit for EMR scanning any pertinent documentation (e.g., consults, hospitalizations) that confirm the basis and sound rationale for anticoagulation.
- 5. Specify in the EMR Anticoagulation Template any special alerts or bleeding risks.
- 6. Although the primary responsibility of the Anticoagulation Clinic staff, document in EMR Anticoagulation Template any changes in patient status and/or changes in Coumadin/Warfarin, if there are interim changes that you are aware of.
- 7. Make certain the EMR Medication Module is current, with the exception of dosing regimen of Coumadin/Warfarin; such dosing is confined to the EMR Anticoagulation Template.
- 8. Respond in a timely manner to EMR INBOX tasks assigned by NAC staff related to anticoagulation issues.
- 9. Maintain the expectation that the patient will attend the clinic on a monthly basis, at a minimum, if they expect the NEON provider to be involved in management decisions related to their anti-coagulation.
- 10. If you know that a patient has missed their last NAC appointment, provide only a minimum quantity (7-10 doses) of Coumadin/Warfarin to tide them patient over. The discharge plan should include an appointment with the NAC within 7-10 days.

Responsibility of Primary Care Provider in working with an Outside Anticoagulation Clinic (OAC):

- 1. Order and prescribe a maintenance dose of Coumadin/Warfarin.
- 2. Specify in the EMR Anticoagulation Template the INR range and duration of therapy.
- 3. Specify in EMR Anticoagulation Template the medical condition that is the basis/reason for anticoagulation.
- 4. Obtain and submit for EMR scanning any pertinent documentation (e.g., consults, hospitalizations) that confirm the basis and sound rationale for anticoagulation.
- 5. Specify in the EMR Anticoagulation Template any special alerts or bleeding risks.
- 6. Document in EMR Anticoagulation Template any changes in patient status and/or changes in Coumadin/Warfarin.
- 7. Make certain the EMR Medication Module is current, with the exception of dosing regimen of Coumadin/Warfarin; such dosing is confined to the EMR Anticoagulation Template.
- 8. Document in the 'Comments' section of the EMR Anticoagulation Template where and by whom the patient's anticoagulation therapy needs are being managed; and contact information (phone number and email address information).
- 9. Make certain that the OAC staff has your telephonic and email contact information.

- 10. Respond in a timely manner to all telephone calls and email messages initiated by the OAC staff related to anticoagulation issues.
- 11. Maintain the expectation that patient will attend the OAC on a monthly basis, at a minimum, if they expect the NEON provider to be involved in management decisions related to their anticoagulation.
- 12. Maintain the expectation of OAC staff that they will notify you if the NEON patient is noncompliant with OAC visits or Coumadin/Warfarin therapy regimen.
- 13. If it is known that the patient is non-compliant with OAC visits, provide only a minimum quantity (7-10 doses) of Coumadin/Warfarin to tide a patient over if you know they have missed their Anticoagulation Clinic appointment.
- 14. If it is known that the patient is non-compliant with Coumadin/Warfarin therapy regimen, you are obligated to terminate your involvement in the arrangement with the OAC. This generally means that you should not be involved with writing Coumadin/Warfarin prescription on behalf of the patient. Please refer to the last section of this protocol for guidance on DISMISSING A PATIENT FROM THE ANTICOAGULATION CLINIC.

Chart Coding Responsibility of NEON Provider utilizing an Outside Anticoagulation Clinic (OAC)

- 1. The principle diagnosis (e.g., DVT, atrial fibrillation) for which the OAC NEON patient is on anticoagulation must be listed and tagged as a Chronic Problem.
- 2. V58.61 for "Long-term (current) use of anticoagulants" should be listed and tagged as a **Chronic Problem** for the OAC NEON patient.

Responsibility of Anticoagulation Clinic Staff:

- 1. Based on the Anticoagulation Clinic appointment schedule, make prior contact with the patients in order to ensure the following:
 - a) That they understand the importance of attendance
 - b) To make certain that they are taking their Coumadin/Warfarin as an evening dose
- 2. Upon entry into the Anticoagulation Clinic, ensure the following actions take place:
 - a) Specify in EMR Anticoagulation Template the medical condition that is the basis or reason for anticoagulation and confirm that the indications are appropriate.
 - b) Specify in the EMR Anticoagulation Template the INR range and duration of therapy.
 - c) Obtain and submit for EMR inclusion any pertinent documentation (e.g., consults, hospitalizations) that validate basis/reason for anticoagulation.
 - d) Specify in the EMR Anticoagulation Template any special alerts or bleeding risks.
 - e) Document in EMR Anticoagulation Template any changes in patient status and/or changes in Coumadin/Warfarin.
 - f) Adverse reactions/signs of bleeding are discussed with the patient
 - g) Common interactions with foods and medications are discussed with the patient

- h) Patient is instructed on how to contact Anticoagulation Clinic staff with any potential symptom or initiation of any new medications including prescriptions and OTC medications.
- i) Safety issues are discussed with the patient.
- 3. Document in the EMR that the above items were reviewed and discussed with the patient and/or family.
- 4. Provide patients with educational handouts, based on their level of literacy, about Coumadin/Warfarin therapy, side effects, adverse reactions, and interactions.
- 5. Notify a physician when adverse reactions or excessive anticoagulation occur.
- 6. Respond in a timely manner to EMR INBOX tasks assigned by the patient's primary care provider related to anticoagulation issues.
- 7. Adjust Coumadin/Warfarin dose per Anticoagulation Clinic protocol or a physician's order, if deemed more conservative.
- 8. Schedule patients for office visits to address issues of compliance, bleeding, adverse reactions, communication problems or other problems that are difficult to manage over the telephone.
- 9. Consult with a physician when changes outside of established protocols are necessary.
- 10. Track delinquent patients weekly and provide reminders via telephone or letter as needed.
- 11. Inform the patient's primary care provider regarding patients demonstrating repeated problems with noncompliance.
- 12. Ongoing education and teaching with patients receiving Coumadin/Warfarin therapy.
- 13. Review and update protocols annually with the Medical Director.
- 14. Provide a patient an Anticoagulation Clinic Patient Plan document as part of the discharge process for each clinic visit.

Adopted after Sacramento Heart Anticoagulation Clinic protocols

RECOMMENDED THERAPEUTIC GOALS FOR ORAL ANTICOAGULATION

| Indication | INR | Duration |
|--|-------------|---|
| Prophylaxis of venous thrombosis for high-risk surgery | 2 to 3 | Clinical judgment |
| Treatment of venous thrombosis | | |
| First episode | 2 to 3 | *6 months |
| Recurrence off anticoagulation with warfarin | 2 to 3 | *6 months |
| Ongoing hypercoagulable state (AT-III, protein C or S deficiency, malignancy) | 2 to 3 | Indefinite |
| Recurrence despite adequate anticoagulation | 2.5 to 3.5 | Indefinite |
| Thrombosis associated with antiphospholipid antibody | 3 to 4 | Indefinite |
| Treatment of pulmonary embolism | | |
| First episode | 2 to 3 | 6 months |
| High risk of recurrent embolism | 2 to 3 | Indefinite |
| Prevention of systemic embolism | | |
| Tissue heart valves | 2 to 3 | 3 months |
| Acute myocardial infarction (to prevent systemic embolism)† | 2 to 3 | Clinical judgment |
| Valvular heart disease (after thrombotic event or if the left atrium is greater than 5.5 cm) | 2 to 3 | Indefinite |
| Atrial fibrillation | | |
| Chronic or intermittent | 2 to 3 | Indefinite |
| Cardioversion | 2 to 3 | 3 weeks before and 4 weeks after atrial fibrillation if normal sinus rhythm is maintained |
| Prosthetic heart valves | | |
| Aortic Mechanical | 2.5 to 3.5‡ | Indefinite |
| Aortic Bioprosthetic | 2 to 3 | Clinical judgment (3 mo option) |
| Mitral Mechanical | 2.5 to 3.5‡ | Indefinite |
| Mitral Bioprosthetic | 2 to 3 | 3 months |

INR=International Normalized Ratio.

^{*--} ASA 100 mg PO daily should be considered for life-long therapy after 6 month period of warfarin anticoagulation. (N Engl J Med. 2012;366:1959-1967

^{†--}If oral anticoagulant therapy is elected to prevent recurrent myocardial infarction, an INR of 2.5 to 3.5 is recommended.

^{‡--}Depending on the type of mechanical valve (i.e., caged ball or caged disk) and the valve position (mitral), some patients may benefit from INRs in the upper end of the range.

ORAL ANTICOAGULATION TARGETED INR MAINTENANCE PROTOCOLS

| | TARGET INR 2.0-3.0 | |
|---------|---------------------------|--------------|
| RANGE | ADJUSTMENT | FOLLOW-UP |
| <2.0 | Per protocol | 1-2 weeks |
| 2.0-3.0 | No change | 4-6 weeks |
| 3.1-4.0 | Per protocol | 1-2 weeks |
| 4.1-6.0 | Per protocol | 3-7 days |
| >6.0 | Notify physician | Per protocol |

| | TARGET INR 2.5-3.5 | |
|---------|--------------------|--------------|
| RANGE | ADJUSTMENT | FOLLOW-UP |
| <2.5 | Per protocol | 1-2 weeks |
| 2.5-3.5 | No change | 4-6 weeks |
| 3.6-4.5 | Per protocol | 1-2 weeks |
| 4.6-6.0 | Per protocol | 3-7 days |
| >6.0 | Notify physician | Per protocol |

Risk Factors for Hemorrhagic Complications of Anticoagulation Therapy

- Age greater than 65 years
- Age greater than 75 years with concomitant atrial fibrillation (intracranial hemorrhage)
- History of gastrointestinal bleeding
- Co-morbid disease states:

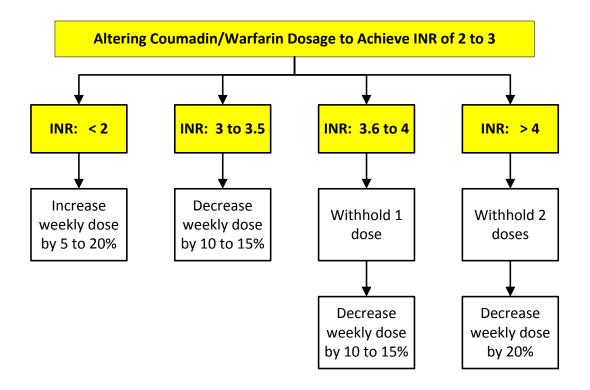
Hypertension

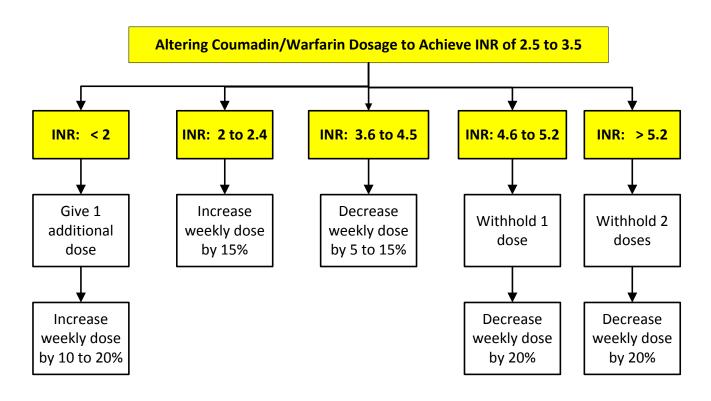
Cerebrovascular disease

Serious heart disease

Renal insufficiency

COUMADIN/WARFARIN ADJUSTMENT DOSE ALGORITHMS





| Sun | Mon | Tues | Wed | Thur | Fri | Sat | Total | Change |
|-------|---------|-------|---------|-------|---------|-------|-------|--------|
| 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | 11 mg | -20% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | ½ tab | 1 tab | 12 mg | -15% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 13 mg | -5% |
| 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 14 mg | 0% |
| 1 tab | 1½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 15 mg | +5% |
| 1 tab | 1 ½ tab | 1 tab | 1 tab | 1 tab | 1 ½ tab | 1 tab | 16 mg | +15% |
| 1 tab | 1 ½ tab | 1 tab | 1 ½ tab | 1 tab | 1 ½ tab | 1 tab | 17 mg | +20% |

Dosing adjustment with 2.5 mg tab strength dosing

| Sun | Mon | Tues | Wed | Thur | Fri | Sat | Total | Change |
|-------|---------|-------|---------|-------|--------|-------|----------|--------|
| 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | 13.75 mg | -20% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | ½ tab | 1 tab | 15 mg | -15% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 15.75 mg | -5% |
| 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 17.5 mg | 0% |
| 1 tab | 1 ½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 18.75 mg | +5% |
| 1 tab | 1 ½ tab | 1 tab | 1 tab | 1 tab | 1½ tab | 1 tab | 20 mg | +15% |
| 1 tab | 1 ½ tab | 1 tab | 1 ½ tab | 1 tab | 1½ tab | 1 tab | 23.75 mg | +20% |

Dosing adjustment with 5 mg tab strength dosing

| Sun | Mon | Tues | Wed | Thur | Fri | Sat | Total | Change |
|-------|--------|-------|---------|-------|---------|-------|---------|--------|
| 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | 27.5mg | -20% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | ½ tab | 1 tab | 30 mg | -15% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 32.5 mg | -5% |
| 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 35 mg | 0% |
| 1 tab | 1½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 37.5 mg | +5% |
| 1 tab | 1½ tab | 1 tab | 1 tab | 1 tab | 1½ tab | 1 tab | 40 mg | +15% |
| 1 tab | 1½ tab | 1 tab | 1 ½ tab | 1 tab | 1 ½ tab | 1 tab | 42.5 mg | +20% |

Dosing adjustment with 7.5 mg tab strength dosing

| Sun | Mon | Tues | Wed | Thur | Fri | Sat | Total | Change |
|-------|---------|-------|---------|-------|---------|-------|----------|--------|
| 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | ½ tab | 1 tab | 41.25 mg | -20% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | ½ tab | 1 tab | 45 mg | -15% |
| 1 tab | ½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 48.75 mg | -5% |
| 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 52.5 mg | 0% |
| 1 tab | 1 ½ tab | 1 tab | 1 tab | 1 tab | 1 tab | 1 tab | 56.25 mg | +5% |
| 1 tab | 1½ tab | 1 tab | 1 tab | 1 tab | 1½ tab | 1 tab | 60 mg | +15% |
| 1 tab | 1 ½ tab | 1 tab | 1 ½ tab | 1 tab | 1 ½ tab | 1 tab | 63.75 mg | +20% |

SCHEDULING FOLLOW-UP NAC VISITS BASED ON TARGETED INR AND PATIENT'S REPORTED INR

| | Target INR 2 to 3 | |
|---------|---------------------------------|-------------------------|
| Range | Adjustment | NAC Scheduled Follow-up |
| < 2 | Per protocol | 1 - 2 weeks |
| 2 - 3 | No change | 4 weeks |
| 2 - 3 | No change for 3 months (stable) | 12 weeks* |
| 3.1 - 4 | Per protocol | 1 - 2 weeks |
| 4.1 - 6 | Per protocol | 3 - 7 days |
| > 6 | Notify PCP/ER referral protocol | Per protocol |

| | Target INR 2.5 to 3.5 | |
|-----------|---------------------------------|-------------------------|
| Range | Adjustment | NAC Scheduled Follow-up |
| < 2.5 | Per protocol | 1 - 2 weeks |
| 2.5 - 3.5 | No change | 4 weeks |
| 2.5 - 3.5 | No change for 3 months (stable) | 12 weeks* |
| 3.6 - 4.5 | Per protocol | 1 - 2 weeks |
| 4.6 - 6 | Per protocol | 3 - 7 days |
| > 6 | Notify PCP/ER referral protocol | Per protocol |

PCP = primary care provider

^{*} National Guideline Clearinghouse: NGC-8926 - Evidence-based management of anticoagulant therapy: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Bibliographic Source(s) Holbrook A, Schulman S, Witt DM, Vandvik PO, Fish J, Kovacs MJ, Svensson PJ, Veenstra DL, Crowther M, Guyatt GH. Chest 2012 Feb; 141(2 Suppl):e152S- 84S. Refer to section on "Maintenance Treatment with VKAs."

MANAGEMENT OF EXCESSIVE ORAL ANTICOAGULATION

| INR & CLINICAL SITUATION | INTERVENTION |
|---|---|
| 6 - 10; no bleeding noted | 1. Omit the next 2 doses. |
| | 2. Repeat INR every 2 - 3 days until INR is in therapeutic range. At that point follow appropriate algorithm noted in prior sections. |
| 6 - 10; significant bleeding | REFER TO ER: Coordinate care subsequent to ER encounter to decide on appropriate dosing schedule. |
| > 10; no bleeding | REFER TO ER: Coordinate care subsequent to ER encounter to decide on appropriate dosing schedule. |
| > 20 or serious bleeding | SUMMON EMS: Coordinate care subsequent to ER encounter to decide on appropriate dosing schedule. |
| Life-threatening bleeding or serious Coumadin/ Warfarin overdose | SUMMON EMS: Coordinate care subsequent to ER encounter to decide on appropriate dosing schedule. |

- 1. The Coumadin clinic staff will always notify the patient's primary care provider if excessive anticoagulation occurs.
- 2. The above guidelines will be followed unless otherwise indicated by the patient's specialist. If other interventions are ordered, it will be documented in the patient's health record.
- 3. Review for signs and symptoms of bleeding will be done on any patient found to have an INR greater than 4.5.
- 4. If signs or symptoms of bleeding are present, the patient's cardiologist and physician will be notified immediately and orders other than the stated protocols will be obtained.
- 5. If it is not possible to obtain an INR at 6 hours post Vitamin K injection, an INR will be obtained as soon as possible without exceeding 18 hours post injection.
- 6. With INR ranges of 6 to 10, it would be acceptable to hold Coumadin/Warfarin until INR declines to a therapeutic range, then resume at lower dose if there are no signs of bleeding and the patient is at very low risk for bleeding or injury.
- 7. INR values greater than 6 will always be checked with repeat analysis prior to administration of Vitamin K.
- 8. Any INR value obtained via fingerstick that is found to be greater than 8 will be repeated using a venous sample prior to administration of Vitamin K.

NEON'S ANTICOAGULATION CLINIC PATIENT MONITORING ROUTINE

The patient may be questioned regarding the following at subsequent visits:

- 1. Compliance with (and confirmation of) recommended dose
- 2. Number of doses missed during the past 5-7 days
- 3. Medications started or discontinued since last visit
- 4. Over the counter medications started or discontinued since last visit
- 5. Herbal products started or discontinued since last visit
- 6. Diet changes since last visit
- 7. Change in exercise routine
- 8. Recent acute illnesses
- 9. Recent use of alcohol
- 10. Peripheral edema
- 11. Recent bruising or bleeding problems
 - Minor bleeding episodes (blood in urine, stool, bleeding gums, repeated nosebleeds, etc)
 - Major bleeding episodes.

Patient Education

Patient education on **initial visit** will include the following:

- a) Drug interaction screening with patient's current drug regimen
- b) Herb interaction screening with herbals the patient may be taking
- c) Dietary considerations
- d) Importance of maintaining anticoagulation
- e) Signs of hypercoagulation
- f) Importance of compliance and follow-up monitoring
- g) Written information about herbal interactions, OTC interactions, dietary Vitamin K content, and Warfarin information will be given to the patient
- h) Importance of wearing some form of medical alert identification.

Follow up education will be conducted on **subsequent visits** as follows:

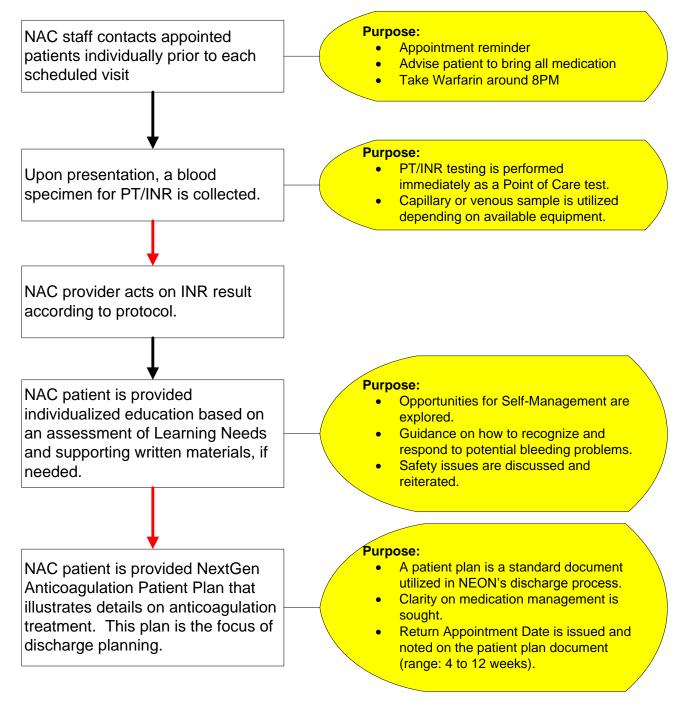
- a) The patient will be questioned about signs of bruising and/or bleeding.
- b) The patient will be offered repeat education to reinforce previous education.
- c) Questions will be answered regarding anticoagulation therapy.
- d) Importance of compliance and follow-up will be reinforced.
- e) Screening for new or discontinued drugs, OTC products, and herbs will be performed.

Chart Coding Responsibility of NEON Anticoagulation Clinic (NAC) Provider

- 1. The **principle diagnosis** (e.g., DVT, atrial fibrillation) for which the NAC patient is on anticoagulation must be listed and tagged as a **Chronic Problem**.
- 2. <u>V58.61</u> for "Long-term (current) use of anticoagulants" must be listed and tagged as a Chronic Problem for the NAC patient.

TYPICAL NEON ANTICOAGULATION CLINIC FLOW

[NAC=NEON Anticoagulation Clinic]



DISMISSING A PATIENT FROM NEON'S ANTICOAGULATION CLINICAL INVOLVEMENT

It is the intent and expressed purpose of NEON to minimize patient harm from the prescribing of anticoagulation therapy in abidance with the Joint Commission's National Patient Safety Goal NPSG.03.05.01. In pursuit of this goal, for various reasons, a patient on anticoagulation therapy may need to be referred elsewhere for the purposes of anticoagulation therapy. There are two reasons (**Dismissal for Non-Adherence** & **Referral due to High Complexity**) described below that NEON's clinical involvement with the patient's anticoagulation might be terminated.

Dismissal for Non-Adherence:

- A. If a patient registered to NEON refuses to participate in an Anticoagulation Clinic (whether NEON or non-NEON-based) and it has been proven, without a doubt, that the patient requires anticoagulation therapy with Warfarin products, patient must be dismissed from NEON's <u>medical</u> practice and referred elsewhere for total medical care rather than simply decline to prescribe the patient anticoagulation therapy. It is possible that another health care provider might have a greater ability and the wherewithal to manage the primary care and anticoagulation needs of the patient (e.g., wide access to point-of-care INR testing).
 - 1. The patient should be supplied a 30-day supply of Coumadin/Warfarin at the current dose with a stern advisement that they must connect with an external provider within 30 days.
 - 2. In addition, a PT/INR should be ordered and the results mailed to the patient upon receipt of the results along with any last recommendations on dosing.
 - 3. Such cases must be referred to the Medical Director in order to make certain that the details of the referral are handled in a manner that does not lend itself to the inference of patient abandonment. The patient will also be sent a certified **Letter of Medical Care Dismissal**.
 - 4. Health insurance companies, where ever applicable, will also be notified.
- B. If a patient demonstrates a pattern of inconsistent attendance to NEON's Anticoagulation Clinic (or an outside Anticoagulation Clinic) that relies on the participation of NEON providers in the prescribing of Warfarin products, the patient <u>must be referred elsewhere</u> for anticoagulation therapy rather than simply decline to prescribe the patient anticoagulation therapy. It is possible that another health care provider may have greater success in achieving medical compliance.
 - 1. The patient can be supplied a 30-day supply of Coumadin/Warfarin at the current dose with a stern advisement that they must find another provider within the date range. However, this should be done with great caution: weighing the overall risks of prescribing this type of medication given the circumstances.
 - 2. In addition, a PT/INR should be ordered and the results mailed to the patient upon receipt of the results along with any last recommendations on dosing.
 - 3. Such cases must be referred to the Medical Director in order to make certain that the details of the referral are handled in a manner that does not lend itself to the inference of patient abandonment. The patient will also be sent a certified **Letter of Concern**.
 - 4. Health insurance companies, wherever applicable and useful, will also be notified.

Referral due to High Complexity

Patients who are deemed too complex (high complexity) for the NEON Anticoagulation Clinic must be referred elsewhere for the management of their anticoagulation needs. In such instances, the NEON primary care provider may continue to serve the other primary medical care needs of the patient; however, they will need to coordinate such care with the external specialty unit that has been delegated to care for the patient's anticoagulation needs. Refer to the section beginning on Page 2 of this protocol entitled "Responsibility of Primary Care Provider in working with an Outside Anticoagulation Clinic (OAC)" for guidance on collaborating with an external provider.

Examples of high complexity are as follows:

- Very erratic INR values, beyond the therapeutic range, necessitating frequent and alternating (up and down) dose changes over a 3-month period.
- Six or more episodes of minor bleeding despite protocol-directed dosing within the previous 3-month period.
- Two or more episodes of severe or significant bleeding within the previous 6-month period necessitating Vitamin K administration.

SPECIAL CIRCUMSTANCES

For the vast majority of patients served by NEON who are on anticoagulation therapy, this protocol should be relevant. However, there are instances whereby exceptions should be made. Nevertheless, such exceptions should not be made by the primary care provider without the consultation of the Medical Director.

A clear opportunity for an exception to this protocol and the need to develop an alternative clinical pathway is in the setting of a bedridden or house-bound NEON patient. In such instances, the NEON PCP is likely working in a collaborative manner with a home visiting nurse provider. If the NEON PCP chooses to participate in the anticoagulation needs of such a patient with such a nurse provider, it is incumbent on the PCP to maintain a close and responsive relationship with the visiting nurse provider. This relationship should not be delegated or signed off to another NEON PCP unless approved by the Medical Director.

As far as clinical responsibilities are concerned, the NEON PCP must complete the required elements of the EMR Anticoagulation Template. The "Comments" section <u>must</u> clearly indicate the nursing agency, their contact information, and the date in which the Medical Director approved this activity.

It should be understood that at the present time NEON is not in the business of home healthcare. If such care is in fact delivered, it should be with the understanding that such care is temporary, until the patient is able to resume ambulatory clinic visits within the NEON network. Therefore, if it is suspected that the patient will remain house-bound for a period of more than 12 weeks days, then the NEON PCP is obligated to refer the patient to an outside medical provider group that is in the business of home healthcare service delivery.