Exhibit EP16.a

Outpatient Anticoagulation Clinic

Purpose:

- To manage oral vitamin K antagonist (warfarin) therapy by evaluating the International Normalized Ration (INR) and instructing patients of appropriate dosage of warfarin
- To assess patients for possible complications related to warfarin therapy
- To provide comprehensive and ongoing education to patients and/or family members about warfarin therapy with specific attention to signs and symptoms to report

Provider skill level:

Anticoagulation providers trained in anticoagulation management: Registered Nurse (RN), Licensed Independent Provider (LIP)

Patient eligibility criteria to enroll into the clinic:

- Patients must have a documented need for warfarin therapy.
- Patients must have documented PCP that practices in that clinic.
- Patients must be able to attend clinic appointments unless other arrangements have been made by the clinic.
- Patients or their caretakers must be willing to be active participants in their health maintenance.
- Patients must be able to travel to and from clinic appointments unless other arrangements have been made.
- Patients must have a documented working telephone number for follow up.
- Patients must have follow up with PCP every 6-12 months (to be determined by the discretion of the LIP.)

Procedure

1. Initial Visit
    a. Initial evaluation of patients will occur after a warfarin referral form has been completed and sent to the clinic by the LIP upon discharge or from their PCP.
    b. Create FYI flag for anticoagulation during initial visit.
    c. Patient will be seen by an anticoagulation provider who will obtain and document the following patient information in EMR.
        i. Indication of warfarin therapy
        ii. Goal INR range
        iii. Past medical/surgical history
        iv. Comprehensive medication list
        v. Allergies
        vi. Date of initiation, anticoagulation therapy received, and duration of warfarin therapy
        vii. Name of Primary Care Physician (PCP)
        viii. Patient telephone number, address, emergency contact
        ix. Dispensing pharmacy name and phone number
    d. Anticoagulation provider will review clinic procedure and enrollment into the outpatient anticoagulation clinic. Patient will receive detailed education regarding warfarin therapy and other related anticoagulation medications.
    e. Learning assessment must be documented in EPIC at initial visit.

f. Baseline INR will be obtained by fingerstick with the CoaguChek or lab Facility in the clinic if no contraindications exist at the discretion of the LIP.
g. Dosage adjustment may be made according to protocol, if necessary.
h. Follow up visit will be scheduled.

2. For patients initiating warfarin or re-starting warfarin therapy **along with** an injectable anticoagulation therapy:
    a. LIP must obtain baseline platelet count and renal function, which should be within normal range prior to initiating or continuing injectable anticoagulant.
        i. LIP will monitor platelet count 5 to 10 days after initiating subcutaneous unfractionated heparin (UFH) or Low Molecular Weight Heparins (LMWH) to assess for heparin induced thrombocytopenia (HIT). See Guidelines for Assessment and Treatment of HIT & HITTS to calculate the 4T score.
    b. Patient should remain on the injectable anticoagulant therapy for a minimum of 5 days and until INR is in therapeutic range for 2 consecutive days (ensuring 2 consecutive days for therapeutic INR for patients with known VTE).

3. Goal INR range
    a. Will be determined by the referring physician or LIP prior to patient hospital discharge and included on warfarin referral form/ambulatory protocol or in the discharge summary if a non-UVA provider is referring the patient to the clinic.

4. Duration of warfarin therapy
    a. Expected duration of warfarin therapy will be determined and documented on the referral form by the PCP.
    b. When therapy has reached the expected discontinuation date, the PCP will be notified and then will determine the need for continuation or discontinuation of warfarin therapy. The decision will be documented in the EMR.

5. Frequency of INR monitoring
    a. INR must be checked within 3 days upon initiation of warfarin therapy then INR monitoring should occur every 3 to 5 days until INR is within therapeutic range for the 2 consecutive readings.
    b. Following the initial titration period, INR monitoring will decrease to at least once weekly for the remainder of their first month of therapy.
    c. When INR is in therapeutic range for 1 to 2 weeks, extend follow-up to every 4 weeks.
    d. INR monitoring will be done within 1 to 2 weeks when INR is out of range, dose adjustments are made, and/or there is a significant change in the patient's health status, medications, or diet.
    e. The RN or LIP may increase or decrease frequency of monitoring as necessary according to Appendix A & B.

general monitoring parameters and frequency of INR will depend on individual patient condition and overall treatment plan

6. Clinic Appointments
    a. Clinic visits are by appointment. If patients are unable to keep an appointment they are to notify the office and reschedule.
    b. Patients will be assessed by the anticoagulation provider regarding:
        i. Any falls or trauma
        ii. Signs/Symptoms of bleeding (epistaxis, gingival bleeding, gross hematuria, hemoptysis, bruising, black/tarry stools)
        iii. Signs/Symptoms of recurring primary event (shortness of breath, chest pain, tender/swollen/red extremities)
        iv. Any changes in medications, dietary habits, or new diagnosis or health status
        v. Compliance with warfarin
        vi. Signs/Symptoms of intolerance of drugs
    c. Patients will have INR checked by fingerstick with the CoaguChek or Lab facility as appropriate.
        i. If result is ≥ 4.0-venous sample must be obtained-sent to lab.
    d. Based upon INR and assessment dosage changes in warfarin therapy will be made if necessary (according to guidelines) and patient will be counseled regarding these changes.
    e. Dosage changes are made in accordance with guidelines and compliance with guidelines are overseen and monitored by the Medical Director of Anticoagulation Network Services.
        i. Any deviation from guidelines must be approved by the patient's PCP of that clinic.
    f. Patient education will be reinforced and reviewed.
    g. Follow up appointment will be scheduled.
    h. Patient will be referred to the PCP or physician on-site for any of the following:
        i. Signs/Symptoms of thrombosis
        ii. Signs/Symptoms of serious bleeding episodes
        iii. Significant adverse drug reactions
        iv. Significantly elevated INR (≥ 5.0) Lab drawn result
        v. Significantly subtherapeutic INR (per maintenance protocol document) with high risk of thromboembolism (i.e. DVT or PE in the last 3 months)
    i. Prescription for warfarin may be renewed by phone by the RN, LIP, or PCP.
    j. All visits and assessment will be documented in the EMR.

7. Phone Patients
    a. Patients who are unable to attend clinic due to immobility, proximity, or patient condition must be accepted by the clinic PCP and identified as requiring off-site management for their anticoagulation needs.
        i. These patients may have their INR drawn by a laboratory, home health nurse, or self testing and are classified as phone patients.
        ii. Clinic will obtain results from the lab, home health nurse, and self-monitoring agency used by the patient and enter these results into the EMR.
        iii. Patient will receive instructions by telephone from the nurse or LIP.
        iv. Patients will be interviewed for complications and education will be reinforced.

8. Patient Education (located: http://www.healthsystem.virginia.edu/docs/per/per1183)
    a. Anticoagulation provider will review the following learning objectives with the patient at the initial visit and use these objectives to assess patient knowledge of warfarin therapy at each clinic visit:
        i. Rationale for warfarin therapy
        ii. How the drug works
        iii. Brand and generic names of warfarin and specify the color and marking of warfarin that the patient will be taking
        iv. Goal INR range and it interpretation of the values
        v. Importance of compliance, close monitoring of INR, and follow up appointments
        vi. Describe the common signs of bleeding and thrombosis
        vii. Outline precautionary measures to decease trauma, bleeding, or falls
        viii. Explain how medication, tobacco, and alcohol may interfere with anticoagulant therapy
        ix. Explain warfarin's effects upon pregnancy and state importance of birth control measure (or abstinence)
        x. State the importance of informing healthcare provider when dental, surgical, or any invasive procedures are planned to occur
        xi. Identify the importance of notifying all healthcare providers of warfarin therapy
        xii. State what to do in an emergency

9. Quality/Dashboard
    a. Monthly monitoring of patients within ordered INR range once stabilized.
        i. Standard-60% of chronic long term patients will remain within range of 1.9-4.0 INR range.

10. No Show Patients/Discharge from ACG therapy management after the following conditions are met:
    a. If patient repeatedly fails to keep clinic appointments, have lab tests done, or take anticoagulation as prescribed the patient may be dismissed from the anticoagulation clinic at the discretion of the clinician.
    b. 2 No shows after phone contact or certified letter sent to patient.
    c. Patient's PCP needs to be notified and made aware of circumstances re: patient's failure to make appointments and/or follow clinician recommendations. PCP needs to agree with termination of care.
    d. Certified letter needs to be sent to patient's home address notifying patient of dismissal from anticoagulation therapy and management.

References

- Kearon C, Akl EA, Comerota AJ, Prandoni P, Bounameaux H, Goldhaber SZ, Nelson ME, Wells PS, Gould MK, Dentali F, Crowther M, Kahn SR. Antithrombotic therapy for VTE disease: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest. 2012 Feb;141(2 Suppl):e419S-94S