ANTICOAGULATION THERAPY MANAGMENT

1. PURPOSE: To develop a structured Anticoagulation Management Program (AMP) and related procedures at the Phoenix VA Health Care System (PVAHCS) that meets the standards identified and set forth in the VHA Directive 1033 dated July 29, 2015. To void previous AMPs anticoagulation related documents and procedures that are not updated to meet VHA Directive 1033 requirements.

2. POLICY: To develop standard operating procedure(s) that provide high-quality, evidence-based management of anticoagulants and reduce the likelihood of patient harm. This policy will support all elements of the Anticoagulation Program Requirements set forth by the Chief Consultant, Pharmacy Benefits Management and will be approved by the Clinical Executive Board (CEB) for implementation at the PVAHCS.

3. DEFINITIONS:

a. **Algorithm:** refers to a standardized care process which outlines steps used to manage a patient's anticoagulation therapy and utilized across the PVAHCS. All algorithms will be evidence-based, approved by the Pharmacy and Therapeutics (P&T) Committee and CEB. An algorithm may be supported by protocols (for example, unfractionated heparin protocols by nursing staff) or Standard Operating Procedures (SOPs). Any actions or processes outlined in algorithms or protocols must be within the scope of practice of the individual performing the function and competency must be assessed on an ongoing basis as appropriate.

b. **Anticoagulant:** refers to a medication that inhibits blood coagulation. Anticoagulants include, but are not limited to, warfarin, unfractionated heparin, low molecular weight heparin, other parenteral anticoagulants (e.g., fondaparinux, argatroban), and direct oral anticoagulants (DOACs) such as dabigatran, rivaroxaban, apixaban, or edoxaban. Medications whose primary purpose is to inhibit platelet function are not included under this definition.

c. **Anticoagulation Management Program:** this is a coordinated program where anticoagulation providers manage anticoagulants for inpatients and outpatients within PVAHCS. In addition to the clinical practice aspect, the program also encompasses broader functions including coordinating policy and quality assurance relevant to anticoagulation management at the PVAHCS.

d. **Anticoagulation Provider:** refers to a provider who is currently trained and skilled in in managing anticoagulant therapy. According to VHA Directive 1033, anticoagulation providers may be clinical pharmacists, Advanced Practice Registered Nurses (APRN), physician assistants, and physicians. The anticoagulation provider is an active member of the anticoagulation management program, responsible to monitor

the quality of his or her clinical practice, and has prescriptive authority defined in their scope of practice or clinical privileges that includes anticoagulants.

e. **Anticoagulation Program Manager:** is a Clinical Pharmacy Specialist that serves as a leader and information resource for the anticoagulation management program. He/she is responsible for ensuring that the program meets all elements in this policy. The Anticoagulation Program Manager collaborates with other services to ensure that PVAHCS is compliant with standards outlined in VHA directive 1033. The Anticoagulation Program Manager is generally a Clinical Pharmacy Specialist with a scope of practice, however other providers may be designated for this role at the PVAHCS.

f. **Pharmacy Anticoagulation Champion:** is an anticoagulation provider, generally a Clinical Pharmacy Specialist that serves to advocate for and support anticoagulation initiatives in the work group and at the facility.

g. **Anticoagulation Support Staff:** refers to a group of professionals assigned to the anticoagulation management program who perform day-to-day operational support functions under the supervision of Anticoagulation Program Manager. Anticoagulation support staff may include, but are not limited to, pharmacy technicians, nurses, health technicians, and clerical associates. At the PVAHCS, anticoagulation support staff shall (1) assist with many of the technical issues associated with the anticoagulation management program under the supervision of an anticoagulation provider, (2) have functional statements, coupled with a competency assessment that accurately reflects the job responsibilities and tasks they perform, and (3) answer and triage patient telephone calls, contact patients who have missed appointments, send letters to patients, communicate with outside laboratories, and other similar tasks (4) other duties as assigned.

h. **International Normalized Ratio (INR):** refers to a standardized measure of the PT, which is used to determine the clotting tendency of blood for a patient receiving warfarin therapy. The INR is the ratio of a patient's PT to a normal (control) sample, raised to the power of the International Sensitivity Index (ISI) value for the reagent system used.

i. **International Sensitivity Index (ISI):** is a measure of Thromboplastin sensitivity to an international standard. Each lot number of Thromboplastin used in Prothrombin or INR testing is assigned its own unique ISI value from the manufacturer.

j. **Parent Facility:** refers to PVAHCS with a three-digit Station Number 644 and includes all community clinics, outreach clinics and other locations where anticoagulation service is delivered to Veterans.

k. **Direct Oral Anticoagulant (DOAC):** encompasses several drug classes, and includes, but is not limited to, dabigatran, rivaroxaban, apixaban, and edoxaban.

DOACs [also referred to as TSOAC (target specific oral anticoagulants) or NOACS (novel oral anticoagulants)] target one or more specific steps in the coagulation.

1) Oral Direct Thrombin Inhibitors: Oral medications that inhibit the coagulation cascade through direct inhibition Thrombin (Factor IIa). Examples include dabigatran etexilate (Pradaxa®). The following are alternative anticoagulants that target one or more specific steps in the coagulation cascade.

2) Anti-Xa Agents: Oral or injectable medications that inhibit the coagulation cascade through inhibition of Factor Xa. Oral examples include rivaroxaban (Xarelto®), apixaban (Eliquis®), and edoxaban (Savaysa®). Injectable examples include fondaparinux sodium (Arixtra®).

3) Low Molecular Weight Heparins (LMWH): Injectable medications that inhibit the coagulation cascade primarily through their effect on Factor Xa, but also to a lesser degree on Thrombin (Factor IIa). Examples include enoxaparin sodium (Lovenox®) and dalteparin sodium (Fragmin®).

4. PROCEDURES:

a. Refer to PVAHCS Anticoagulation Program Standard Operating Procedures and Algorithms:

1) Direct Oral Anticoagulants (DOACs) criteria for use (January 2014 and February 2015)

2) VHA CPPO Pharmacy Benefits Management (PBM) Strong Practice Recommended Warfarin Management Algorithm (Initiation Phase)

3) VHA CPPO PBM Strong Practice Recommended Warfarin Management Algorithm (Maintenance Phase)

b. Refer to Clinical Pharmacy Practice Anticoagulation Program Management. http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Anticoagulation.aspx

c. PVAHCS Anticoagulation Therapy Management program will use the algorithms developed by the Clinical Pharmacy Practice - Anticoagulation Program Management (PBM) for the initiation of warfarin, maintenance of warfarin, peri-procedural management of anticoagulants, and the use of weight-based, unfractionated heparin. http://vaww.infoshare.va.gov/sites/ClinicalPharmacy/Clinical%20Specialty%20Pages/Anticoagulation.aspx.

d. All patients prescribed oral anticoagulants from PVAHCS on an ongoing basis must be managed by the facility Anticoagulation Management Program.

e. All laboratory tests for anticoagulation management will be performed at the PVAHCS laboratory to ensure accuracy of results and data capture.

f. PVAHCS Anticoagulation Management Program will monitor all patients on anticoagulants. The following is a list of evidence-based baseline and ongoing laboratory tests and other measurements recommended by the American College of Chest Physicians, American Heart Association, and medication product labeling:

Anticoagulant	**Laboratory Tests for Baseline and/or Monitoring**
Heparin	Complete blood count (CBC), activated partial thromboplastin time (aPTT), anti-Xa.
LMWH and Factor Xa Inhibitors (Fondaparinux):	CBC, serum creatinine
Warfarin:	CBC, prothrombin time (PT), international normalized ratio (INR).
DOACs	CBC, serum creatinine, liver function tests.

g. Anticoagulation providers will ensure follow-up for patients identified with a critical drug-drug (or other clinically relevant) interaction with anticoagulant medications in a timely manner of critical drug interactions.

Items	**Responsibility**
Assessment of the interactions	Anticoagulation providers OR ordering provider
Anticoagulant dose adjustments	Anticoagulation providers OR ordering provider
Order and follow-up of subsequent laboratory tests	Anticoagulation providers OR ordering provider
Communications	Anticoagulation providers OR ordering provider

h. Female, male-to-female transgender and other special cases: currently there are no VHA Directives, Handbooks, policies, or procedures in that specifically addresses anticoagulation for these Veteran populations. It is for this reason a Physician Champion (or a Physician), as applicable, will evaluate and document in CPRS the risks (for example, bleeding leading to uterine and/or other genital tract complications, fertility, pregnancy, and lactation in women of reproductive age) prior to prescribing a DOAC or warfarin. Anticoagulation Therapy Management providers such as a Clinical Pharmacist, Physician Assistant or a Physician (no trainees) may follow such patients at PVAHCS following the initial assessment and starting of warfarin/DOAC by the Physician Champion (or a Physician).

i. All INR results will be evaluated in accordance with VHA Directive 2009-019, *Ordering and Reporting Test Results*.

j. Critical INR values will be addressed as soon as possible to include communication with patient or caregiver. Other actions such as dose changes reordering INR will be documented in CPRS within 24 hours of the critical INR result.

k. Anticoagulation providers will add the appropriate International Classification of Diseases (ICD) Diagnosis Codes to the problem list of patients on long-term anticoagulation therapy. In addition, appropriate Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) codes may be used as applicable. The current ICD-10 diagnosis code for "Long-term current use of anticoagulants" is Z79.01.

l. Anticoagulation providers will perform periodic risk-benefit assessments for all patients receiving anticoagulant therapy and managed in the anticoagulation management program. Recommended components of the risk-benefit assessment will be performed according to Appendix A, VHA Directive 1033.

m. To minimize the risk associated with incorrect tablet strength and dosing errors with warfarin, patients will be prescribed one tablet strength of warfarin to reduce the risk for confusion. Outpatient pharmacy will:

1) limit the number of warfarin strengths dispensed for outpatient prescriptions to 1 mg, 3 mg, and 5 mg tablets;

2) creating a separate outpatient orderable items for each warfarin tablet strength; and

3) providing written patient education with instructions whenever a dose change is made.

n. Outpatient prescriptions for warfarin will be labeled appropriately to avoid patient confusion with changes to the instructions for use.

o. Education.

1) Patients and or caregiver(s)

a) All anticoagulation providers will customize education based on comprehension, age, hearing, vision, language barriers, etc. and document in CPRS.

b) Anticoagulation Management Program will develop educational material for patients receiving oral anticoagulants as recommended in VHA Directive 1033 (Appendix A). Educational material along with oral counseling will be offered to patients and/or caregiver(s) to include:

(1) Indication for therapy.

(2) Daily dosage.

(3) The management of missed doses.

(4) Proper tablet identification (for warfarin).

(5) Interactions (drug, diet, and disease).

(6) Risks associated with falling.

(7) The importance of medication adherence.

(8) Monitoring requirements (specifically for warfarin).

(9) Proper medication storage (specifically for dabigatran).

(10) The dangers of using medication from different sources (especially for warfarin).

c) Patients and caregivers will be educated to (a) recognize the signs and symptoms of bleeding and thromboembolic events and what to do if such an event occurs; and (b) inform the anticoagulation provider when changes in medications occur or upcoming procedures are expected and about acute illness, major changes in diet, or upcoming travel (for warfarin).

2) Anticoagulation providers and other staff.

a) The educational plan for clinical staff directly involved in caring for patients receiving anticoagulation therapy will include (see also the TMS modules on anticoagulation):

(1) Reviewing and assessing the results of anticoagulation quality assurance program and performance improvement activities;

(2) Education based on locally identified learning needs;

(3) Review of new algorithms or policies, emerging information regarding anticoagulants, or anticoagulant topics identified as important to the facility;

(4) VHA recommended educational programs; and

(5) Education may be provided in forums such as staff meetings,

newsletters, grand rounds, external programs or other venues.

5. RESPONSIBILITIES:

a. The Medical Center Director is responsible for ensuring that:

1) A policy exists that meets all standards identified in VHA Directive 1033, Appendix A to ensure safe management of anticoagulation therapy.

2) An Anticoagulation Management Program manages inpatients and outpatients on anticoagulants.

3) An Anticoagulation Program Manager has been designated to lead the PVAHCS Anticoagulation Management Program and has been provided with appropriate time to fulfill these duties consistent with the complexity of the local anticoagulation program.

4) Adequate staff and resources are allotted for the Anticoagulation Management Program to include anticoagulation providers, nurses, pharmacy technicians, registered dietitian/nutritionists, program administration, and information technology support, as appropriate. This includes ensuring anticoagulation providers have adequate anticoagulation support staff to work at the top of their license and maximize operational efficiency.

5) The Anticoagulation Management Program has an appropriate staff-to-patient ratio to provide safe and appropriate care as defined in Appendix A of the VHA Directive 1033.

6) Competencies specific to Anticoagulation Management are established for anticoagulation providers and clinical staff directly involved in caring for patients receiving anticoagulation therapy at the PVAHCS. Competencies, at a minimum, must include knowledge of standard terminology, pharmacology of anticoagulants, monitoring requirements, dose calculations, common side effects, nutrient interactions, and drug to drug interactions associated with anticoagulation therapy.

7) Care is coordinated for traveling patients on anticoagulants in accordance with VHA Handbook 1101.11, *Coordinated Care for Traveling Veterans*, or subsequent policy issue.

8) PVAHCS uses programmable infusion pumps for inpatients receiving parenteral anticoagulants, including, but not limited to unfractionated heparin, argatroban, and bivalirudin.

9) PVAHCS employs standardized, evidence-based, algorithms for the management of patients on anticoagulants as defined in Appendix A of the VHA Directive 1033.

10) Anticoagulants are included on the PVAHCS list of high-alert medications.

b. Chief of Staff (COS) is responsible for ensuring that:

1) A physician is identified as Anticoagulation Management Champion, to be actively involved in defined components of the anticoagulation management program. This champion will serve collaboratively with the Pharmacy Anticoagulation Management Champion to advocate for and provide consultation on anticoagulation and thrombosis issues, and support anticoagulation initiatives at the PVAHCS.

2) Policies governing the provision of Anticoagulation Management are approved by the CEB. Anticoagulation providers will collaborate in the development of PVAHCS guidelines/algorithms for anticoagulants.

3) Clinical staff directly involved in caring for patients receiving anticoagulation therapy (e.g., support staff, nurses, clinical pharmacists, pharmacy technicians, registered dietitian/nutritionists, APRNs, physician assistants, and physicians) are educated on the importance of anticoagulation safety and its associated risks, as well as the principles of anticoagulation management, as appropriate.

4) Quality assurance (QA) information for the PVAHCS anticoagulation management program reports are reviewed through the Pharmacy and Therapeutics (P&T) Committee and CEB.

5) Competencies of non-pharmacist anticoagulation providers and clinical staff directly involved in caring for patients receiving anticoagulation therapy to include minimum components outlined in paragraph 4.a.(6) of VHA Directive 1033.

6) Anticoagulation providers at the PVAHCS have adequate anticoagulation support staff to maximize operational efficiency.

c. Chief of Pharmacy Service is responsible for ensuring that:

1) A clinical pharmacist anticoagulation provider is identified as the Pharmacy Anticoagulation Management Champion to be actively involved in defined components of the anticoagulation program at the facility level. This champion may be the Anticoagulation Program Manager and serves to advocate for and support anticoagulation initiatives at the facility.

2) Competency of clinical pharmacist anticoagulation providers and pharmacy technicians who serve in the anticoagulation management program to include the minimum components outlined in paragraph 4.a.(6) of the VHA Directive 1033 (Page 2).

3) Clinical pharmacists that serve as anticoagulation providers have adequate anticoagulation support staff to work at the top of their license and maximize operational efficiency. Tasks that support the duties of the clinical pharmacist may be performed by pharmacy technicians or other anticoagulation support staff to maximize time for clinical pharmacists to perform direct patient care.

4) Inpatient Pharmacy dispenses oral unit dose products, pre-filled syringes, or pre-mixed infusion bags for anticoagulants to inpatients when these types of products are available.

5) The number of concentrations and quantities of heparin vials stocked in patient care and procedural areas are limited to the minimum needed to meet patient

care needs. No multi-dose heparin product more concentrated than 5,000 units per milliliter is stocked without the prior approval of the Chief of Pharmacy.

6) Safe storage of anticoagulants in automated dispensing cabinets. If multiple strengths or concentrations of the same anticoagulant are stored in the same automated dispensing cabinet, they need to be stored in separate drawers (or single access cubie) and clearly labeled as high alert medications.

7) Anticoagulation Therapy Management Program policy is supported by Standard Operating Procedures that are consistent with the operational and quality assurance requirements delineated in Appendix A of the VHA directive 1033.

d. Chief of Nutrition and Food Services is responsible for ensuring that:

1) Warfarin is included in Nutrition and Food Services' established food and medication interaction program.

2) A process is established to notify Nutrition and Food Services of inpatients receiving meal services that are also receiving warfarin therapy.

3) Nutrition and Food Services responds according to its established food and medication interaction program to patients receiving meal services and warfarin therapy. Meal planning and educational efforts are focused on steady Vitamin K intake, individualized to meet the overall health needs, and supporting an adequate dietary reference intake for Vitamin K.

e. Director of Pathology and Laboratory Medicine Service (P&LMS) is responsible for:

1) Ensuring a critical INR value is established and listed in the Laboratory Veterans Health Information System and Technology Architecture (VistA) software package.

2) Establishing a Standard Operating Procedure, in conjunction with the Anticoagulation Program Manager, for the communication of critical INR results from the laboratory to the ordering provider (or designee).

3) Ensuring the correct International Sensitivity Index (ISI) value for the lot number of thromboplastin, currently in use, is entered into the coagulation testing instrumentation.

4) Ensuring there is documentation of periodic monitoring to ensure the entered value remains accurate.

5) Ensuring the correct Geometric Mean Prothrombin Time (PT) is calculated for the current lot number of thromboplastin and is entered into the coagulation testing instrumentation as required for calculation of the INR. The Geometric Mean PT needs to be recalculated with each change of lot number of thromboplastin reagent.

6) Ensuring the availability of reliable testing of heparin levels (factor Xa levels), heparin associated antibodies and a serotonin release assay for the evaluation of heparin induced thrombocytopenia.

7) Educating staff providing clinical services in an outpatient anticoagulant clinic.

f. Anticoagulation Program Manager (APM) jointly reports to the Chief of Pharmacy, who reports to the Deputy Chief of Staff. APM is responsible for the following functions related to the anticoagulation program at the PVAHCS:

1) Serves as a leader or co-leader and subject matter expert in the oversight, design, implementation, and function of the anticoagulation management program.

2) Develops standard operating procedures and algorithms related to use of anticoagulants at the PVAHCS in all inpatient and outpatient areas.

3) Promotes learning and unified practice for the anticoagulation management program through activities such as educational initiatives, regular staff meetings, and journal clubs.

4) Coordinates and reports quality assurance activities and results for the anticoagulation management program through the P&T Committee and CEB.

5) Coordinates educational program for clinical staff directly involved in caring for patients receiving anticoagulation therapy (e.g. clinical pharmacists, pharmacy technicians, registered dietitians/nutritionists (if applicable), nurses, APRNs, physician assistants, and physicians).

6) Ensures availability of appropriate patient education materials and classes, as

a) Managing anticoagulation patients in accordance with PVAHCS policy including, but not limited to, coordination of anticoagulation management for patients transitioning between care settings (e.g., inpatient to outpatient), peri-procedural use anticoagulation, and traveling Veterans (outpatient clinical pharmacists).

b) Serving as subject matter experts on anticoagulation management to patients and health care professionals throughout the facility.

c) Delivering initial and ongoing patient and family education that includes the importance of follow-up monitoring, compliance issues, dietary restrictions, and potential for adverse drug reactions and interactions.

d) Conducting appropriate and periodic risk-benefit assessments for all patients receiving anticoagulant therapy and communicating recommendations to the original referring provider and/or Patient Aligned Care Team (PACT) provider as appropriate.

e) Performing and/or facilitating the day-to-day operations of the anticoagulation management program.

f) Reporting, as per local policy, adverse drug events (ADE), close calls, and any unsafe conditions of which they are aware, even though the conditions have not yet resulted in an adverse event or close call to the facility Patient Safety Manager (PSM) in accordance with VHA Directive 1070, *Adverse Drug Event Reporting and Monitoring*, or subsequent policy issue

g) Quality Assurance:

(1) Continuous quality assurance will be done to identify opportunities for improvements and effectiveness of the anticoagulation program at the PVAHCS. The Anticoagulation Program Manager will report to the P&T and CEB on a quarterly basis the tracking and trending of INR values. At minimum, the report will delineate the proportion of patients:

(a) in therapeutic range;

(b) that have not had an INR in the last 42 days;

(c) with pathologic bleeding events;

(d) with thromboembolic events;

(e) close calls and near misses associated with an anticoagulant which are reported through the facility ePER process

h) The Anticoagulation Program Manager or designee will track, trend, analyze and report to P&T (and CEB) the Adverse Drug Events (ADEs) associated with an anticoagulant in accordance with the VHA Directive 1070.

6. RESPONSIBLE BOARD: Clinical Executive Board

7. REFERENCES:

a. VHA Directive 1033, Anticoagulation Therapy Management, dated July 29, 2015.

b. VHA Directive 1070, Adverse Drug Event Reporting and Monitoring dated September 12, 2014.

c. VHA Directive 1088, Communicating Test Results to Providers and Patients dated October 7, 2015.

d. VHA Handbook 1100.19, Credentialing and Privileging dated October 15, 2012.

e. VHA Handbook 1101.10, Patient Aligned Care Team (PACT) Handbook dated February 5, 2014.

f. VHA Handbook 1101.11, Coordinated Care for Traveling Veterans dated April 22, 2015.

g. VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures dated January 29, 2016.

h. VHA Handbook 1108.05, Outpatient Pharmacy Services dated June 16, 2016.

i. VHA Directive 1108.06, Inpatient Pharmacy Services dated February 8, 2017.

j. VHA Handbook 1108.11(1), Clinical Pharmacy Services dated July 1, 2015.

k. Antithrombotic Therapy and Prevention of Thrombosis, 9th edition: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. CHEST. 2012; 141(2): February Supplement.

l. National Patient Safety Goals 2018, The Joint Commission Comprehensive Accreditation and Certification Manual, March 11, 2018.

8. RESCISSION: Policy Memorandum 119-22 Anticoagulation Therapy Management, dated April 2017.

9. ATTACHMENTS: None

10. FOLLOW-UP RESPONSIBILITY: Chief of Pharmacy

11. EXPIRATION DATE: March 2021

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