
ANTICOAGULATION THERAPY MANAGEMENT

1. PURPOSE:

To outline the policy and procedures to achieve maximum therapeutic effectiveness and safety for all patients receiving anticoagulation therapy within the VA Black Hills Health Care System (VABHHCS).

2. POLICY:

A Pharmacy-run Anticoagulation Service manages and monitors all therapeutic anticoagulation therapy for VABHHCS patients, inpatients and outpatients. Providing high-quality, evidence-based management of anticoagulants reduces the likelihood of patient harm.

3. RESPONSIBILITIES:

A. A physician has been identified as the Anticoagulation Management Champion, to collaborate with the anticoagulation program manager, advocate for and provide consultation on anticoagulation issues and support anticoagulation initiatives at the facility level.

B. An Anticoagulation Program Manager has been designated to lead the medical facility's anticoagulation management program.

C. Anticoagulation Providers manage anticoagulation patients in accordance to VA BHHCS policy and Pharmacy Standard Operating Procedures (SOPs).

D. Anticoagulation Support Staff manage the day-to-day operations of the clinic and support Anticoagulation Providers as appropriate.

4. PROCEDURE:

A. All outpatients receiving an anticoagulant from VA BHHCS will receive initial education and management, as appropriate, from the Anticoagulation Clinic.

1) CHOICE prescriptions will NOT be required to be managed by the Anticoagulation Clinic.

2) Eligible patients residing at the State Veterans Home (SVH) will receive anticoagulants from the VA and clinical monitoring services will be provided by the SVH contract facility.

B. Inpatients receiving an anticoagulant from BHHCS will be managed by Pharmacy Service, based on intent:

1) Therapeutic anticoagulation:

a) All therapeutic anticoagulants will be managed by Pharmacy Service

2) Prophylaxis anticoagulation:

a) LMWH or heparin for VTE prophylaxis will NOT be managed by Pharmacy

Service

b) All other anticoagulants used for prophylaxis will be managed by Pharmacy

Service

C. Patients residing in a long term/extended care facility.

1) Contract facility: Patients will NOT be managed by the VA Anticoagulation Clinic. Anticoagulant monitoring and dose adjustment will be done by the facility's supervising clinician as part of the VA contracted services.

2) Contract facility:

a) Warfarin, LMWH: VA Anticoag Clinic will manage patients if the facility and patient agree to the terms in the "Acknowledgment of Patient Responsibilities and Anticoagulation Clinic Operations" specifying that anticoagulant dosing and lab recommendations be taken only from VA Anticoag Clinic staff. If the facility and/or patient wish for the facility's supervising clinician to manage anticoagulation therapy, patient's anticoagulant medication will need to be obtained privately.

b) TSOACs (Target Specific Oral Anticoagulant): Patients will NOT be managed by the VA Anticoagulation Clinic, however, the patient may receive the medication from the VA. Medication will be ordered by the VA primary care provider.

D. Patients will be referred to the Anticoagulation Clinic via CPRS Anticoagulation Clinic consult entered by the provider or designee.

1) There are a few circumstances where a consult is not required, including short-term use (< 14 days) of prophylaxis dose LMWH or TSOACs following orthopedic surgery, inpatients on prophylactic dose LMWH for prophylaxis, etc. Each case will be addressed individually.

2) Patients referred to the Anticoagulation Clinic must have a Primary Care Provider (PCP) assume responsibility for overseeing the management of the patient's medical and/or surgical problems. The provider is responsible for initiating anticoagulant therapy and entering a consult, as above. The PCP will be periodically consulted to clarify therapy concerns. In the event that the patient does not have a PCP assigned, a licensed individual practitioner will be responsible to place the Anticoag consult.

E. The Anticoagulation Provider in the Anticoagulation Clinic will communicate with the provider, when appropriate, to discuss concerns, clarify goals of therapy or indications, discuss therapeutic endpoints, communicate risk versus benefits, and recommend doses of anticoagulants used within the BHHCS.

F. A risk versus benefit assessment will be performed by the patient's PCP, or designee, or Anticoagulation Provider, at least annually for all outpatients receiving anticoagulants as clinically appropriate.

G. Anticoagulation providers must add the appropriate International Classification of Diseases (ICD) Diagnosis Codes to the problem list of patients on long-term anticoagulation therapy.

H. The Anticoagulation Provider performing anticoagulation monitoring will order the necessary labs as outlined in Pharmacy SOPs at baseline and ongoing.

I. VA BHHCS does not allow INR self-testing for patients taking warfarin therapy.

J. Competencies specific to anticoagulation management are established for anticoagulation providers and clinical staff directly involved in caring for patients receiving anticoagulation therapy.

K. The medical facility ensures care is coordinated for traveling patients on anticoagulants in accordance with VHA Handbook 1101.11, Coordinated Care Policy for Traveling Veterans, or subsequent policy issue.

L. VA BHHCS employs standardized, evidence-based, algorithms for the management of patients on anticoagulants. Drug-specific algorithms are outlined in Pharmacy SOPs, with P&T oversight.

M. Warfarin is included the Nutrition and Food Services' established food and medication interaction program, refer to Pharm-05 and NFS-105 policies.

N. Patients receiving anticoagulants from the VA BHHCS will be required to sign a document acknowledging receipt of information on AC clinic operations and outlining the responsibilities of the patient for safe and effective care. If a patient or their designee refuses to sign, anticoagulants will need to be filled outside of the VA BHHCS at the patient's expense (Appendix 1: Acknowledgment of Patient Responsibilities and Anticoagulation Clinic Operations). Patients who fail to comply with anticoagulation monitoring as outlined in the agreement will have their case reviewed with their PCP and an appropriate action taken as discussed and determined by their PCP (Appendix 2: Anticoagulation Clinic No Show Policy).

O. All patients admitted to VABHHCS acute care will have a Venous Thromboembolism (VTE) risk assessment performed by the admitting/attending physician within the first 24 hours of admission.

P. Anticoagulants are considered high-alert medications and are listed as such in the facility's High Risk Medication Policy (Pharm-01).

Q. Critical drug-drug interaction with anticoagulant medications.

1) Anticoagulation providers are notified in a timely manner by finishing pharmacists of critical drug interactions or the critical drug-drug interaction report.

2) Anticoagulation providers will manage the critical drug-drug interactions and consult with ordering provider as appropriate.

R. Lab

1) Critical lab values are called to Anticoagulation Clinic Providers, according to facility policy COS-74.

a) After hours, critical lab values are called to the ER/UC provider, as appropriate.

2) Lab procedures will address specific requirements for anticoagulant-related lab testing (i.e. INR, aPTT, etc.).

3) Certain lab tests uncommonly used to manage anticoagulants that are not available in-house can be ordered as send outs.

5. DRUG SPECIFIC REQUIREMENTS:

A. Warfarin: National contract generic brand will be dispensed.

1) Outpatient: 5mg or 2mg strengths will be utilized for all patients, unless extenuating circumstances require the use of 1mg tablets. Tablets will be split per facility policy unless extenuating circumstances exist (i.e. blindness, dexterity problems, assisted living facility policies).

2) Inpatient: all strengths will be available via unit-dose packaging.

B. Low Molecular Weight Heparin (LMWH): Enoxaparin is currently the preferred agent at VABHHCS. Pre-filled syringes will be used at all times possible.

C. Heparin: 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 or designee. Pre-mixed heparin infusion bags will be utilized as available by manufacturer. Programmable infusion pumps will be utilized for administration of parenteral heparin.

D. TSOACS: All strengths will be available, inpatient doses via unit-dose packaging.

E. Other:

1) Fondaparinux: Pre-filled syringes will be used at all times possible.

2) Argatroban: Programmable infusion pumps will be utilized for administration.

6. QUALITY ASSURANCE (QA):

A. An on-going quality assurance program evaluates anticoagulation safety practices at VABHHCS. This is completed in an effort to identify practice improvements, ensure appropriate action is taken to improve practice, and measure the effectiveness of those actions on a regular basis. Results are reported to P&T.

B. All patients managed in the Anticoagulation Clinic are entered into the Anticoagulation Management Tool (AMT).

1) Time in therapeutic range (TTR), bleeding events, clotting events will be entered in AMT and reports will be generated quarterly and reported to P&T.

2) AMT reports will be utilized to ensure patients on warfarin have an INR obtained or are scheduled for an INR every 42 days. Non-compliance is documented in CPRS and AMT.

C. Adverse reactions entered into CPRS will be tracked and reported according to VAADERS procedures.

7. DEFINITIONS:

A. **Algorithm.** The term algorithm refers to a standardized care process which outlines steps used to manage a patient's anticoagulation therapy and utilized across the facility. Algorithms must be evidence-based, approved by the Pharmacy and Therapeutics (P&T) Committee and ECMS, and follow the guidance included in this directive. An algorithm may contain protocols which are outlined in policy that outline specific actions to be implemented based on patient parameters by designated individuals for anticoagulation patient care

management, e.g., unfractionated heparin protocols by nursing staff. 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. The term 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 target-specific anticoagulants (TSOAC) such as dabigatran, rivaroxaban, or apixaban. For purposes of this directive, the term "anticoagulant" refers to anticoagulation therapy or long-term anticoagulation prophylaxis (e.g., atrial fibrillation) and does not include routine situations in which short-term prophylactic anticoagulation is used for venous thromboembolism prevention (e.g., related to procedures or hospitalization). In addition, medications whose primary purpose is to inhibit platelet function are not included under this definition.

C. Anticoagulation Management Program. The term anticoagulation management program, often commonly referred to as an "anticoagulation clinic", refers to a coordinated program where anticoagulation providers manage anticoagulants for inpatients and outpatients within the facility. 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 facility.

D. Anticoagulation Provider. The term anticoagulation provider refers to a provider who is currently trained and skilled in managing anticoagulant therapy. Anticoagulation providers at VA BHHCS are clinical pharmacy specialists (CPS). 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. The anticoagulation program manager is an anticoagulation provider that serves as a leader for the anticoagulation management program and is responsible for ensuring that the program meets all elements in this directive. This individual maintains a high standard for continuing education in the area of anticoagulation therapy and serves as a local subject matter expert regarding anticoagulation management. The anticoagulation program manager collaborates with other services to ensure that the anticoagulation management program meets all standards outlined in this directive. The anticoagulation program manager is generally a clinical pharmacist with a scope of practice; however other providers may be designated based on local facility needs.

F. Anticoagulation Support Staff. Anticoagulation support staff refers to a group of professionals assigned to the anticoagulation management program who perform day-to-day operational support functions. Anticoagulation support staff at VA BHHCS are clinical pharmacy technicians. Anticoagulation support staff may assist with many of the technical issues associated with the anticoagulation management program under the supervision of an anticoagulation provider. All anticoagulation support staff must have functional statements, coupled with a competency assessment that accurately reflects the job responsibilities and tasks they perform. Responsibilities may include, but are not limited to, answering and triaging

patient telephone calls, contacting patients who have missed appointments, sending letters to patients, communicating with outside laboratories, and other similar tasks.

G. Bridge Therapy. Bridge therapy is the temporary use of a short and immediate acting injectable anticoagulant (usually a heparin) during periods when the INR level is sub-therapeutic (e.g., when warfarin therapy is started) or when warfarin is being held in order to perform invasive procedures (peri-procedural bridging).

H. International Normalized Ratio (INR). INR is 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 ISI value for the reagent system used.

I. Target Specific Oral Anticoagulant. A Target Specific Oral Anticoagulant (TSOAC) encompasses several drug classes, and includes, but is not limited to, dabigatran, rivaroxaban, and apixaban. TSOAC refers to oral anticoagulant medications that target one or more specific steps in the coagulation cascade.

8. REFERENCES:

Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines, February 2012. CHEST 2012.

VHA Directive 1033 Anticoagulation Therapy Management

Consensus Guidance to Ensure the Safe Use of Anticoagulants; July 2008. National VA High Alert Anticoagulant Workgroup, VHA Pharmacy Benefits Management Services, and the Medical Advisory Panel

9. RESCISSION: BHHCS Pharm 101—21 Anticoagulation Clinic, dated 4/28/09.

10. DATE OF COMPLETE REISSUANCE: January 2019

11. FOLLOW-UP RESPONSIBILITY: Chief of Pharmacy; Pharmacy & Therapeutics Committee.

Concurrence chain includes:

Primary Care Service Line,
Specialty Care Service Line,
Pharmacy;
Nursing,
NFS,
Diagnostics,
Organizational Improvement



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Director

APPENDIX A:

VA Black Hills HealthCare System Acknowledgment of Patient Responsibilities and Anticoagulation Clinic Operations

Patient responsibilities:

A. I understand that anticoagulation therapy can only be safe and effective if I cooperate fully with my medical providers at the VA Black Hills Health Care System. My responsibilities as a patient include:

1. Taking warfarin, enoxaparin, dabigatran, rivaroxaban or apixaban as instructed by the Anticoagulation Clinic, only receiving this medication from the VA.

2. Having lab tests as directed by the Anticoagulation Clinic, including adherence to monitoring at least every 42 days or 6 months depending on anticoagulation medication.

3. If I am having my Anticoagulation labs drawn at an outside facility, it is my responsibility to make sure that my most recent results are faxed to this clinic on the day drawn. I also must provide the name, address and telephone number of this private facility to the Anticoagulation Clinic. Any outside laboratory costs will be at my own expense unless I receive prior approval through the

4. Notifying the Anticoagulation Clinic when I am unable to keep the appointment as scheduled.

5. Reminding all my medical providers that I am taking an anticoagulant medication.

6. Informing the Anticoagulation Clinic when I:

a. **Have any changes in my medications; prescription including antibiotics, over-the-counter, "natural"/herbal products or vitamins.**

b. **Experience a significant change in my health or an acute illness.**

c. **Change my address and/or phone number(s).**

d. **Need to temporarily stop my anticoagulation medication as instructed by any provider (examples: dentist, private doctor, etc.).**

B. I understand that if I fail to comply with prescribed treatment regimens or engage in other behaviors that impair safe and effective delivery of care, I may be discharged from the Anticoagulation Clinic at the VA Black Hills Health Care System. Examples of unsafe behavior that may result in my discharge from clinic include:

1. **Patients who prove themselves to be unreliable in keeping their appointments, as evidenced by missing THREE consecutive appointments, THREE appointments in a SIX month period and/or not adhering to the Anticoagulation Clinic No Show Policy.**

2. **Repeated non-adherence to dosing recommendations including excessive alcohol use, refusing to have appropriate monitoring (at least every 42 days) or refusing to meet with the Anticoagulation Clinic staff as directed.**

3. **Not providing the VA Black Hills HealthCare System with my most recent labs (INR) in a timely manner if my labs are obtained outside the VA Black Hills HealthCare System.**

4. Patients whose anticoagulation medication is adjusted by a non-VA provider will be discharged from clinic into the care of the outside provider to ensure safe and effective care.

C. I understand I have a right to accept or not to accept anticoagulation therapy from the VA Black Hills Health Care System.

By signing this treatment agreement, I am **accepting** the anticoagulation therapy and agree to participate in my treatment plans as outlined in this agreement, allowing lab scheduling by letter as decided by the clinic for my safety. _____(patient initials)

D. Copy of agreement given to patient.

Patient Signature: _____ Date: _____

Printed Name/last 4 SSN: _____

APPENDIX B:

Anticoagulation Clinic No Show Policy

A. When a patient no shows to the Anticoagulation Clinic, the Pharmacy Technician (CPhT) will attempt to call the patient daily for up to three days. If the patient does not return the message(s) and/or cannot be reached the CPhT will:

- 1) Enter a No-Show note in CPRS and Anticoagulation Management Tool (AMT).
- 2) Each day the technician attempts to call the patient and does not contact them, he/she will enter an addendum on the original No-Show note.
- 3) After three days, the CPhT will enter a No-Show Letter outlining as stated above and mail to patient.
- 4) If the patient does not have labs drawn or contact the Anticoagulation Clinic, the CPhT will complete the process, as above, for a second time.
- 5) If after three days no labs results are obtained and this is documented in CPRS, the CPhT give the patient case to the Anticoagulation CPS for further action. The CPS will:
 - a) Evaluate current prescription status of warfarin/LMWH. Prescription may be discontinued, placed on 'HOLD,' or refills edited depending upon clinical judgment.
 - b) Enter a second No Show Letter to include above information with Primary Care Provider as a co-signer, if appropriate.
 - c) Evaluate patients' need to continue warfarin therapy and discuss as appropriate with Primary Care Provider. The Primary Care Provider or their designee will be responsible for assessing the appropriateness of continuing anticoagulation therapy.
 - d) A social work consult will be considered to assist with contacting patient.
- 6) At next appointment:
 - a) Patient will be reminded of the importance of keeping anticoagulation clinic appointments.
 - b) Patient education needs will be re-evaluated by CPS with reinforcement of education as appropriate.

B. There will be cases where above policy is not applicable, exceptions to the above may be appropriate as determined by the CPS. Examples: certain fee basis patients with lab only available on certain days of the week, recent critical INR, new patients on warfarin, no address/no phone, etc.