



PHARMACY NEWSCAPSULE

Department of Health Services | Division of Quality Assurance

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New Oral Anticoagulant (NOAC) Monitoring

One of the most considerable differences between warfarin and the new oral anticoagulants (NOACs) is the elimination of International Normalized Ratio (INR) monitoring. Because the NOACs work further down in the coagulation cascade and have a much faster onset of action, the need for close monitoring of prothrombin time is eliminated. However, because these medications are so new, they are not available in generic form and are, therefore, quite expensive. These agents also do not have specific antidotes if major bleeding does occur nor long term data on safety and efficacy.



Administration

The administration of these drugs is not complex; however, there are a few key parameters to follow for each drug, which are listed below.

- **Pradaxa** (dabigatran) – Take with a full glass of water, with or without food. Do not crush or chew. Swallow whole. **Must store in original container; use within four months of opening.**
- **Xarelto** (rivaroxiban) – 10 mg tablets may be taken with or without food; 15 mg and 20 mg tablets should be taken **with food** at approximately the same time each day. Tablets may be crushed and are stable in water or applesauce for up to four hours.
- **Eliquis** (apixaban) – Take with or without food. May crush and suspend tablets in 60 mL D5W for nasogastric tube administration; administer immediately after preparation.
- **Savaysa** (edoxaban) – May be taken with or without food.

Dose Adjustments

Dose adjustments are crucial in certain populations. If a resident has severe renal impairment, the anticoagulant is not excreted from the kidneys as efficiently, causing an increased concentration of drug in the body, increasing risk for bleeds and, even worse, death. Below are considerations for dosing adjustments in each of the available new oral anticoagulants.

- **Pradaxa** – Renal adjustments, depending on indication and CrCl
- **Xarelto** – Renal adjustments, depending on indication and CrCl
Moderate or severe hepatic impairment or any hepatic disease associated with coagulopathy: Avoid Use
- **Geriatrics** – No adjustment necessary
- **Eliquis** – Renal adjustments, depending on indication, age, body weight, and serum creatinine
Severe hepatic impairment: Use not recommended
- **Savaysa** – Renal adjustments, depending on indication and CrCl
Moderate or severe hepatic impairment: Use not recommended
Dose decrease adjustments needed for body weight 60 kg or less



Monitoring

Monitoring patients who are on NOACs is still imperative, even though INRs are no longer needed. Bleeding continues to be a concern in these patients and the following signs and symptoms should be considered when assessing a resident's risks:

- **Bleeding** – Bruising, bleeding of the gums when brushing teeth, coughing or vomiting up blood, blood in the urine or stools, black tarry stools, nosebleeds, elevated INR
- **Stroke** – Sudden changes in vision, sudden onset of extreme headaches, sudden dizziness, numbness on one side of the body, sudden confusion
- **Clotting** – Increase in swelling of the legs, pain in the calves, shortness of breath, chest pain. Addition of any new medications, whether prescription or over-the-counter, should always be discussed with the resident's physician, before being administered for the first time, to conclude that a drug interaction is not evident.

Drug Interactions

Drug interactions are still a concern with NOACs; however, the amount of drug-drug interactions is much less than those with warfarin. Drugs that have a potential for causing bleed such as NSAIDs, antiplatelet agents, and other anticoagulants, should be avoided as this will increase the risk of bleed if used in combination. P-glycoprotein (P-gp) inducers should also be avoided in combination with the NOACs, as they can decrease the effectiveness of the NOAC and potentially cause clotting.

Special Considerations

The NOACs are NOT approved for use in patients with mechanical heart valves. This specific area has not yet been studied and, therefore, has no evidence supporting its use in this population.



Consultant Corner

Doug Englebert, R.Ph.

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An assisted living surveyor was asked how to address unit dose requirements at an Adult Family Home for a stroke patient who was switched to an all liquid medication regimen.

Only CBRFs without an RN, practitioner, or pharmacist supervising medication administration are required to package meds in unit dose. AFHs, CBRFs (with supervision), and RCACs are not required to package and label medications in unit dose.

Licensed Adult Family Homes – Wis. Admin. Code § DHS 88.07(3)(a) Every prescription medication shall be securely stored, shall remain in its original container as received from the pharmacy, and be stored as specified by the pharmacist.

Community-Based Residential Facilities – Wis. Admin. Code § DHS 83.37(1)(c) Packaging. The CBRF shall develop and implement a policy that identifies the medication packaging system used by the CBRF. Any pharmacy selected by the resident whose medications are administered by CBRF employees shall meet the medication packaging system chosen by the CBRF. This does not apply to residents who self-administer medications.

Wis. Admin. Code § DHS 83.37(2)(c) Medication administration not supervised by a registered nurse, practitioner or pharmacist. When medication administration is not supervised by a registered nurse, practitioner, or pharmacist, the CBRF shall arrange for a pharmacist to package and label a resident's prescription medications in unit dose. Medications available over-the-counter may be excluded from unit dose packaging requirements, unless the physician specifies unit dose.

Residential Care Apartment Complexes – Wis. Admin. Code § DHS 89.13(22) "Medication management" means oversight by a nurse, pharmacist, or other health care professional to minimize risks associated with use of medications. Medication management includes proper storage of medications; preparation of a medication organization or reminder system; assessment of the effectiveness of medications; monitoring for side effects, negative reactions, and drug interactions; and delegation and supervision of medication administration.