Reference Guide with Warfarin Therapy

Use of warfarin requires close monitoring to avoid adverse consequences

Warfarin remains the most widely used anticoagulant agent in long term care, largely due to the ease of oral administration and low cost. However, management of warfarin therapy can be challenging, with multiple factors affecting how the medication acts in the body. Variability in diet, disease processes, and drug interactions lead to increasing INR, placing the resident at risk for bleeding.

Challenges with warfarin therapy:

- Complexity of Dosing
- Variable patient response
- Drug-Drug Interactions
- Drug-Food Interactions
- Narrow Therapeutic Range
- Required INR testing

Warfarin therapy should be monitored with a frequency as determined by clinical circumstances, duration of use, and stability of monitoring results of the individual resident. From a regulatory perspective a facility may be noncompliant with F329 if there is a failure to monitor warfarin therapy appropriately, or if there is failure to respond to actual /potentially clinically significant adverse consequences related to the use of warfarin when the PT/INR exceeds the target goal.

Decisions on reversal of warfarin therapy depend on the level the INR and the presence or absence of bleeding. Our reference guide that outlines:

1. Elevated INRs and Treatment of Anticoagulant Related Bleeding
2. Regulated Guidance for F329 and Deficiency Categorization

Elevated INRs and Treatment of Anticoagulant-Related Bleeding

Adapted from AACP CHEST Guidelines 2012

Resident Status	INR Greater than Therapeutic, but < 4.5	INR 4.6-10	INR > 10
Elevated INR+ No Significant Bleeding	• Reduce or skip warfarin dose. • Monitor INR. • Resume warfarin when INR therapeutic. • Dose reduction may not be needed if only slightly above therapeutic range.	• Hold 1 to 2 doses of warfarin. • Monitor INR. • Resume warfarin at lower dose when INR therapeutic. • Vitamin K not routinely recommended if no evidence of bleeding. • Vitamin K can be used if urgent surgery needed (<5 mg, with additional 1 to 2 mg in 24 hrs if needed) or bleeding risk is high (1 to 2.5 mg).	• Hold warfarin and give vitamin K 2.5 to 5 mg PO, even if not bleeding. • Monitor INR. • Resume warfarin at lower dose when INR therapeutic. • Can give IV formulation of vitamin K orally (mix with orange juice to improve taste).
Warfarin-Associated Major Bleeding	Prothrombin complex concentrate suggested over fresh frozen plasma. *(FFP disadvantages: slower onset, risks of allergic reaction and infection transmission, longer preparation time, higher volume.)* • Addition of vitamin K 5 to 10 mg by slow IV infusion suggested.		

Additional Information:

- Depending on patient condition/indication for anticoagulation, if INR over-corrected, consider heparin or low molecular weight heparin until INR therapeutic.
- In all cases, INR will need to be monitored frequently until it is back in the therapeutic range.
- Resume warfarin at an appropriately adjusted dose once the INR is back in the therapeutic range.
- If INR <0.5 above therapeutic range, continue current dose and check INR within one to two weeks.

Source: Holbrook A, Schulman S, Witt DM, et al. Evidence-based management of anticoagulant therapy: antithrombotic therapy and prevention of thrombosis, 9th ed: American College of Chest Physicians evidence-based clinical practice guidelines. Chest 2012;141(Suppl 2):e152S-84S.

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Warfarin/INR Monitoring- Regulatory Guidance for F329: Unnecessary Medications

Relevant Criteria for F329 : Unnecessary Medications

Inadequate Monitoring - Failure to carry out the monitoring that was ordered or failure to monitor for clinically significant adverse consequences

Example: Use of warfarin in conjunction with:

- Inadequate or absent monitoring of PT/INR during treatment
- Failure to recognize/monitor increased risk, when resident takes other medications that are known to increase the risk of bleeding or to interact with warfarin

Adverse Consequences – Examples of noncompliance related to adverse consequences include, but are not limited to:

- Failure to respond to actual or potentially clinically significant adverse consequences related to the use of warfarin, when the PT/INR exceeds the target goal.

F 329 Deficiency Categorization- Examples Involving Warfarin / INR

Severity Level 4 : Immediate Jeopardy to Resident Health or Safety	• Failure to assess or respond appropriately for a resident taking warfarin who had an elevated INR of 9 or greater with or without bleeding, or the elevated INR persisted without assessment/follow-up.	• Failure to monitor PT/INR for a resident on anticoagulant therapy in accordance with current standards of practice and to recognize and/or respond to a life threatening adverse consequence related to anticoagulation.
Severity Level 3: Actual Harm that is Not Immediate Jeopardy	• Facility failure to take appropriate action in response to an INR greater than 4 and less than 9 for a resident who is receiving warfarin until spontaneous bruising or frank bleeding occurs, resulting in the need to transfuse or hospitalize the resident.	
Severity Level 2: No Actual Harm with Potential for More Than Minimal Harm that is Not Immediate Jeopardy	• Facility failure to take appropriate action for a resident who has an INR greater than 4 and less than 9 without any bleeding.	• Failure to monitor INR for a resident who has been stabilized on warfarin, but who has not had bleeding.

Source: State Operations Manual Appendix PP - Guidance to Surveyors for Long Term Care Facilities (Rev. 107, 04-04-14)

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