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TO: Medical Staff, House Staff, Patient Care Centers,
and Outpatient Clinics

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RE: Laboratory assay for apixaban monitoring

The UCM Coagulation Laboratory has validated a new assay for the measurement of the Xa direct oral anticoagulant (DOAC) apixaban. This assay uses the anti-Xa methodology, with apixaban-specific calibrators.

Please see UCM policy PGP-37 for DOAC administration and monitoring. Apixaban does not significantly prolong the PT or aPTT and normal screening coagulation lab values should not be assumed to reflect lack of significant apixaban effect.

As of 4/29/2020, the apixaban assay will be available 6AM-11PM, 7 days per week. If samples are sent during off-hours, they will be processed and frozen for analysis on the next shift.

The apixaban assay's current measurable range is 25 ng/mL to 450ng/mL. Apixaban was FDA approved without defined therapeutic ranges. Peak plasma apixaban concentrations are typically reached approximately 3-4 hours following oral administration. Apixaban half-life is 11-12 hours, assuming normal renal function.

Apixaban dosage varies depending on the indication. Depending on the dosing regimen, on-treatment C_{max} and C_{min} levels have been measured/interpolated to be as follows:

2.5 mg, twice daily:

- C_{max} geometric mean 62.3 ng/mL (29.7-153.2 ng/mL 5th to 95th percentile)
- C_{min} geometric mean 21.0 ng/mL (11.0-89.5 ng/mL 5th to 95th percentile)

5 mg, twice daily:

- C_{max} geometric mean 128.5 ng/mL (58.6-302.2 ng/mL 5th to 95th percentile)
- C_{min} geometric mean 49.6 ng/mL (21.7-176.5 ng/mL 5th to 95th percentile)

10 mg, twice daily:

- C_{max} geometric mean 329.8 ng/mL (111.4-572.4 ng/mL 5th to 95th percentile)

- C_{min} geometric mean 103.8 ng/mL (41.1-334.5 ng/mL 5th to 95th percentile)

Douxflis J et al. *JTH*. 2018. 16:209.

Frost et al. *Br J Clin Pharmacol*. 2013;76:776–86

Byon W et al. *CPT Pharmacometrics Syst Pharmacol*. 2017. 6:340–349

However, actual target goals depend upon intended anticoagulation intensity and dosing schedules for the individual patient.

Apixaban cannot be accurately measured in plasmas showing bilirubin levels >15 mg/dL (due to positive bias) or hemoglobin levels >0.6 g/dL (due to negative bias). Samples with plasma showing gross icterus or hemolysis will be rejected.

For questions, please contact Krzysztof Mikrut, Laboratory Manager, at 773-702-1315, or Geoffrey Wool, MD PhD, Medical Director, at 773-926-1455.