


Name of Policy: <u>Therapeutic Drug Monitoring</u> Policy Number: 3364-133-98 Department: Pharmacy Approving Officer: Senior Hospital Administrator, Chair of P&T Responsible Agent: Director of Pharmacy Scope: University of Toledo Medical Center	 Effective Date: 9/29/2022 Initial Effective date: 12/1/2013
<input type="checkbox"/> New policy proposal <input type="checkbox"/> Minor/technical revision of existing policy <input checked="" type="checkbox"/> Major revision of existing policy <input type="checkbox"/> Reaffirmation of existing policy	

(A) Policy Statement

To provide a condensed guideline for obtaining drug levels. This policy was approved by the Medical Executive Committee on September 28, 2022.

(B) Policy Purpose

Establish criteria for pharmacists to order a drug level or appropriate monitoring laboratory parameter.

(C) Procedure

1. A pharmacist may order a drug level or an appropriate monitoring laboratory if criteria is met in Attachment A: Pharmacist Ordering of Labs and Tests
2. If any criteria are questionable or unable to be evaluated, no orders will be placed by the pharmacist and recommendations, or follow-up questions will be communicated with the provider.
3. Pharmacist will place order for lab in the electronic medical record as a written order under the patient’s attending physician or under the physician who ordered the pharmacy consult (if applicable).
4. Pharmacist will log their activity into pharmacy intervention software and flag for follow up until result is returned.
5. Critical lab results are paged to the patient’s caregiver (RN, MD, and/or midlevel)
6. Pharmacist will communicate recommendations verbally to physician. Escalation policy to be followed to communicate verbally to physician.
7. Pharmacist will document recommendations and results of physician conversation in pharmacy intervention software and in the patient electronic or paper chart

Attachment A

Attachment A: Pharmacist Ordering of Labs and Test

Laboratory	Criteria for ordering	Frequency of ordering	Management of pharmacist generated results
Serum Creatinine (SCr)	Patient on renally eliminated medication	May order if Scr has not been obtained in previous 24 hours	Evaluate Scr and BUN and adjust renally eliminated medications as appropriate per renal dosing policy
BUN	Patient on renally eliminated medication	As clinically necessary	
INR	Patient receiving Prothrombin Complex Concentrate (PCC) (Kcentra™)	For reversal of coagulation factor deficiency induced by Vitamin K antagonists: obtain INR prior to Kcentra administration, 30 minutes after Kcentra infusion, then every 4 hours for the first 12 hours after Kcentra	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary per RM-23 (Kcentra) and RM-26 (warfarin)
	Patient receiving warfarin	Baseline INR with subsequent daily INRs	Pharmacist will evaluate INR, Albumin, and/or CBC and make recommendations to the provider, or order appropriate warfarin dose if consulted to manage therapy (RM-26)
Albumin	Patient receiving warfarin	As clinically necessary	
CBC with differential	Patient receiving warfarin, enoxaparin, fondaparinux, heparin	As clinically necessary	
	Patient on clozapine (Clozaril)	Monitor WBC and ANC at baseline and at least weekly for the first 6 months of treatment, if WBC and ANC remain acceptable the frequency of monitoring can decrease based on product guidelines	The pharmacist will evaluate CBC results and contact the physician if clozapine discontinuation, and/or more frequent laboratory monitoring is necessary
PTT	Patient on heparin or Argatroban	Prior to initiation and as per standardized dosing protocols	Pharmacist may evaluate PTT and make recommendations, or make appropriate dose

			adjustments if consulted to manage therapy (RM-06 argatroban)
Factor Xa Level	Patient on enoxaparin	As clinically necessary	Pharmacist will evaluate results and make recommendations to the provider, or order appropriate enoxaparin dose if consulted to manage therapy per procedure 058-IPP
Aminoglycoside levels	Patient receiving aminoglycoside	As clinically necessary	The pharmacist will evaluate results and make necessary changes.
Vancomycin levels	Patient receiving vancomycin	As clinically necessary	The pharmacist will evaluate results and make necessary changes.
Serum digoxin level	Patient receiving digoxin	As clinically necessary. Digoxin concentrations should be drawn at least 6-8 hours after the last dose (optimally 12-24 hours after a dose)	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary per RM-39
Serum potassium	Patient receiving digoxin	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary.
	Patient initiated on dofetilide	Prior to initiation of therapy per RM-52	
	Patient receiving tolvaptan (RM-02, nonformulary)	As clinically necessary	
Serum Magnesium	Patient receiving digoxin	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary.
	Patient being initiated on dofetilide	Prior to initiation of therapy per RM-52	
Serum sodium	Patient receiving Tolvaptan (RM-02, nonformulary)	Every 6 hours for the first 24 hours of therapy, then daily	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary.
ECG	Patient being initiated on dofetilide	Prior to initiation of therapy per RM-52	The pharmacist in conjunction with the physician involved in the management of

			tikosyn initiation will review results and make necessary adjustments
Total† and Free Phenytoin Concentrations	Patient receiving phenytoin or fosphenytoin	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary per RM-36
†Note: if available, free phenytoin concentrations should be obtained in patients with renal impairment and/or hypoalbuminemia; if free phenytoin concentrations are unavailable the pharmacist may order an albumin level and calculate an adjusted phenytoin concentration			
Total and free valproic acid levels	Patient receiving valproic acid or derivatives	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary per RM-43
Serum Ammonia			
Liver Enzymes (ALT, AST, Alk Phos)	Patient receiving valproic acid or derivatives; tolvaptan; azole antifungal agents; or caspofungin	Valproic acid or derivatives: As clinically necessary. Tolvaptan: at baseline and as clinically necessary Azole antifungal agents: As clinically necessary. Caspofungin: As clinically necessary.	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary
Creatine phosphokinase (CPK)	Patient receiving daptomycin	Initiated on daptomycin and a CPK level has not been ordered within the past week; CPK level should be monitored weekly but may be ordered at a shorter interval if the patient has recently been on a statin or has renal failure	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary. If CPK levels exceed 5x normal in symptomatic patients, or 10x normal in asymptomatic patients consider discontinuing daptomycin.
Serum Theophylline levels	Patient receiving theophylline or aminophylline	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary.
Plasma Uric Acid levels	Patient receiving rasburicase	4 hours after rasburicase	The pharmacist will evaluate results and

		administration, then every 6-8 hours until Tumor lysis syndrome (TLS) resolution	contact the physician when discontinuation of therapy is indicated
Osmolality gap (plasma sodium, plasma glucose, BUN and measured osmolality)	Patient on lorazepam infusion	As clinically necessary for infusions lasting greater than 48 hours	Pharmacist will evaluate for propylene glycol toxicity and contact the physician if changes in therapy are necessary.
MRSA Screen Probe (MRSA DNA rapid polymerase chain reaction (PCR])	Patients with a working diagnosis of pneumonia who are also prescribed an anti-MRSA antibiotic	As close to the initiation of the anti-MRSA therapy as possible, and within 24 hours of initiation	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary.
Carbamazepine Level, Free and Total	Patient receiving carbamazepine	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary per RM-37
Lithium Level	Patient receiving lithium	As clinically necessary	The pharmacist will evaluate results and contact the physician if changes in therapy are necessary per RM-41
Iron Study with Ferritin (includes serum iron, total iron binding capacity [TIBC], and serum ferritin)	Patient receiving epoetin alfa (Epogen, Procrit)	Should be assessed prior to administration of epoetin alfa. New iron studies should be ordered if no results from previous 3 months are available	The pharmacist will evaluate results and contact the physician if iron supplementation is necessary. Please refer to the Epoetin alfa (Epogen, Procrit) Prescribing Guideline.
Triglycerides	Patients receiving propofol (Diprivan) infusion	As clinically necessary (suggested: baseline and every 3-5 days while on propofol) OR if triglycerides are elevated (>500 mg/dL)	The pharmacist will evaluate results, and if triglycerides are elevated (>500 mg/dL) the pharmacist will notify provider for further management/possible alternative sedation strategies
Anti-Xa Level	Patients receiving low molecular weight	As clinically necessary (consider	The pharmacist will evaluate results and

	heparin [e.g., enoxaparin (Lovenox)]	monitoring in morbid obesity (BMI >40), severe renal impairment, and pregnancy)	will either automatically adjust the dose per P&T policy OR contact the physician if changes in therapy are necessary
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<p>Approved by:</p> <p><u>/s/</u> Lindsey Eitnien PharmD, BCPS, AAHIVP Director of Pharmacy</p> <p><u>10/17/2022</u> Date</p> <p><u>/s/</u> Russell Smith Pharm D, MBA, BCPS Senior Hospital Administrator</p> <p><u>10/17/2022</u> Date</p> <p><u>/s/</u> Zohaib Ahmed, MD Chair Pharmacy and Therapeutics Committee</p> <p><u>11/3/2022</u> Date</p> <p><i>Review/Revision Completed By:</i> Pharmacy</p>	<p>Review/Revision Date: 5/2016 2/2020 6/2022</p>
	<p>Next Review Date: 09/2025</p>
<p>Policies Superseded by This Policy:</p>	

It is the responsibility of the reader to verify with the responsible agent that this is the most current version of the policy.