OUR LADY OF THE LAKE REGIONAL MEDICAL CENTER						
Policy Manual: Pharmacy		rmacy	Section:	Patient Care Services		
Title:	Tikosyn® (dofetilide)		Policy Reference #:	PH-02-22		
Title.			Supersedes #:			
Date of Origination:		10/13/2014	Last Date Reviewed:	12/05/2023		
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PURPOSE:

The purpose of this policy is to establish guidelines for Tikosyn® (dofetilide) administration at Our Lady of the Lake Regional Medical Center (OLOLRMC).

DEFINITIONS:

Tikosyn® (dofetilide) is a class III antiarrhythmic agent FDA approved for the maintenance of normal sinus rhythm in patients with chronic atrial fibrillation or atrial flutter of longer than 1 week duration who have been converted to normal sinus rhythm. Tikosyn® may also be used for conversion of atrial fibrillation and atrial flutter to normal sinus rhythm.

Automatic Pharmacy Consult

Pharmacy will be automatically consulted on all inpatient Dofetilide orders. Clinical pharmacists will automatically monitor and manage Dofetilide treatment dosing, as well as potassium and magnesium replacement in all admitted patients using P&T approved **Dofetilide** (**Tikosyn®**) **Pharmacy Consult Protocol on Initiation and Monitoring.**

POLICY:

- A. Tikosyn® may be ordered in the hospital as a continuation of therapy from home or as a new addition to the patient's medication regimen
 - 1. New initiation of Tikosyn shall only be ordered by cardiology (including mid-level providers)
 - 2. Continuation of a home medication may be ordered by any service line provider.
- B. Prior to verifying a Tikosyn® order (continuation of home medication or new addition), the pharmacist must also review the patient's chart to assess renal function, electrolyte status, drugdrug interactions, QTc interval, and appropriateness of therapy.
 - 1. If no labs are available, the pharmacist shall verify and dispense one dose only and subsequently order a stat BMP and magnesium level.
 - 2. If serum creatinine, potassium, and magnesium are available within the previous 30 days, the pharmacist shall use the reported labs for assessment of the ordered dose but ensure that a BMP plus magnesium has been ordered for the following day.

3. Electrolytes may be ordered by pharmacist and replaced per protocol as follows:

Potassium Level	Dose to be given
3.7 to 3.9 mg/dL	Potassium chloride 20 mEq PO x 1 dose
3.0 to 3.6 mg/dL	Potassium chloride 40 mEq PO x 1 dose
less than 3.0 mg/dL	Contact provider

Magnesium Level	Dose to be given
1.9 to 2.4 mg/dL	Magnesium oxide 400mg PO x 1 dose
1.5 to 1.8 mg/dL	Magnesium sulfate 2 gm IV x 1 dose
1 to 1.4 mg/dL	Magnesium sulfate 4gm IV x 1 dose
less than 1 mg/dL	Contact provider

C. Creatinine clearance should be calculated using the Cockcroft-Gault equation and actual body weight. The provider must approve dose adjustments. The Tikosyn® dose should be adjusted for renal function as follows:

Calculated Creatinine Clearance	Tikosyn® Dose
> 60 ml/min	500 mcg twice daily
40-60 ml/min	250 mcg twice daily
20- 39 ml/min	125 mcg twice daily
< 20 ml/min	CONTRAINDICATED

- D. The prescribing physician may choose to initiate Tikosyn® at a lower dose than recommended based on the patient's clinical status and baseline QTc.
- E. Tikosyn is contraindicated with ondansetron, verapamil, hydrochlorothiazide, cimetidine, ketoconazole, trimethoprim/sulfamethoxazole (or trimethoprim alone), prochlorperazine, megestrol, and dolutegravir. Tikosyn is also contraindicated in patients with congenital or acquired prolonged QT syndromes, a baseline QT interval or QTc greater than 440 msec (500 msec in patients with ventricular conduction abnormalities), and severe renal impairment (CrCl less than 20 ml/min).
- F. Every patient initiated on Tikosyn® shall be counseled by a pharmacist and given a 7 day supply of medication prior to discharge from the hospital.
 - 1. Weekday Discharge: On the day of discharge, an electronic prescription for a 7 day supply of Tikosyn® will be send to RXOne pharmacy where the prescription will be filled. The filled prescription along with the Tikosyn® medication guide and patient education packet shall be hand-delivered to the patient by the RXOne pharmacy team member responsible for counseling the patient.
 - a. Upon completion of the counseling session, the patient will acknowledge receipt of counseling by signing a pre-printed label, which should be returned to the RXOne pharmacy and retained for records.

2. Weekend Discharge: For discharge between 9 am – 12 noon(on Saturdays). An electronic prescription for a 7-day supply of Tikosyn® will be send to RXOne pharmacy where the prescription will be filled. The filled prescription along with the Tikosyn® medication guide and patient education packet shall be hand-delivered to the patient by the RXOne pharmacy team member responsible for counseling the patient.

For weekend discharge after 12 noon, the nurse will bring a prescription for a 7-day supply of Tikosyn® to the inpatient pharmacy where the prescription will be filled. The filled prescription along with the Tikosyn® medication guide and patient education packet shall be hand-delivered to the pharmacist responsible for counseling the patient.

a. Upon completion of the counseling session, the patient will acknowledge receipt of counseling by signing a pre-printed label, which should be returned to the main pharmacy and retained for records.

G. Tikosyn® initiation protocol:

- 1. Patient must be placed on telemetry and baseline QTc must be obtained. The pharmacist shall utilize an EKG obtained within the 24 hours prior to initiation.
 - a. If QTc > 440 msec, (500 msec in patients with ventricular conduction abnormalities) Tikosyn is contraindicated, call physician.
 - b. If $QTc \le 440$ msec, continue with initiation protocol
- 2. Calculate creatinine clearance using the Cockcroft-Gault equation for estimating glomerular filtration rate. Actual body weight should be used when calculating creatinine clearance. Pharmacist must contact provider for adjustments.
- 3. Pharmacist shall replace electrolytes and contact prescriber if needed.
- 4. Check QTc 2-3 hours after first dose.
 - a. If increase in QTc \leq 15%, continue current dose.
 - b. If increase in QTc > 15% or > 500 msec, decrease dose (see below):

Dosing adjustments for QTc		
If starting dose is	Adjusted dose is	
500 mcg BID	250 mcg BID	
250 mcg BID	125 mcg BID	
125 mcg BID	125 mcg Daily	

- 5. If at any time after the second dose, QTc increases to greater than 500 msec, Tikosyn® should be discontinued. Call physician.
- 6. Any further dose adjustments may be made at the discretion of the ordering physician.

H. Tikosyn continuation of home medication protocol:

1. Patient must have an EKG obtained upon admission. Telemetry monitoring not required. (refer to Medications Requiring Special Monitoring) If the QTc is greater than 500 msec, Tikosyn should be discontinued. Call physician.

- 2. Calculate creatinine clearance using the Cockcroft-Gault equation for estimating glomerular filtration rate. Actual body weight should be used when calculating creatinine clearance. Pharmacist must contact provider for adjustments
- 3. Pharmacist shall replace electrolytes and contact prescriber if needed.
- 4. Any further dose adjustments may be made at the discretion of the ordering physician

References:

- 1. Pfizer Laboratories. Tikosyn® Package Insert. January 2014. Revised 2019
- 2. Dofetilide (Lexi-Drugs): Lexicomp®
- 3. Dofetilide (Tikosyn®) Pharmacy Consult Protocol on Initiation and Monitoring. <u>Tikosyn clinical consult protocol.pdf (formweb.com)</u>