SPECIALTY GUIDELINE MANAGEMENT

TIKOSYN (dofetilide) dofetilide (generic)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

- A. FDA-Approved Indications
 - Maintenance of normal sinus rhythm (delay in time to recurrence of atrial flutter/atrial fibrillation [AF/AFI]) in patients with AF/AFI of greater than one week duration who have been converted to normal sinus rhythm^{1,2}
 - 2. Conversion of AF/AFI to normal sinus rhythm^{1,2}

B. Compendial Uses

- 1. Supraventricular tachycardia^{3,4,6}
- 2. Ventricular tachyarrhythmia³⁻⁵

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR APPROVAL

- **A.** Atrial Flutter/Atrial fibrillation^{1,2} Authorization of 12 months may be granted for the maintenance of, or conversion to, normal sinus rhythm after atrial flutter or atrial fibrillation.
- **B.** Supraventricular tachycardia^{3,4,6} Authorization of 12 months may be granted for treatment and prevention of supraventricular tachycardia.
- **C.** Ventricular tachyarrhythmia³⁻⁵ Authorization of 12 months may be granted for treatment and prevention of ventricular tachyarrhythmia.

III. PRESCRIBER SPECIALTIES

This medication must be prescribed by or in consultation with a cardiologist.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

V. REFERENCES

1. Tikosyn [package insert]. New York, NY: Pfizer Inc.; August 2019.

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- 2. Dofetilide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; December 2020.
- 3. Micromedex Solutions [database online]. Cambridge, MA: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. Last Modified: March 22, 2022. Accessed April 4, 2022.
- 4. Clinical Consult. CVS Caremark Clinical Program Review: Focus on Cardiovascular Disease Programs; September 2012.
- 5. Clinical Consult. CVS Caremark Clinical Program Review: Focus on Cardiovascular Disease Programs; October 2010.
- Page RL, Joglar JA, Caldwell MA, et al. 2015 ACC/AHA/HRS Guideline for the Management of Adult Patients With Supraventricular Tachycardia. A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am Coll Cardiol. 2016;67(13).

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