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

- 1. 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
- 2. Conversion of AF/AFI to normal sinus rhythm

B. Compendial Uses

- 1. Supraventricular tachycardia
- 2. Ventricular tachyarrhythmia

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

II. CRITERIA FOR APPROVAL

1. Atrial Flutter/Atrial fibrillation

Authorization of 12 months may be granted for the maintenance of, or conversion to, normal sinus rhythm after atrial flutter or atrial fibrillation.

2. Supraventricular tachycardia

Authorization of 12 months may be granted for treatment and prevention of supraventricular tachycardia.

3. Ventricular tachyarrhythmia

Authorization of 12 months may be granted for treatment and prevention of ventricular tachyarrhythmia.

III. CONTINUATION OF THERAPY

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

IV. REFERENCES

- 1. Tikosyn [package insert]. New York, NY: Pfizer Inc.; August 2019.
- 2. Dofetilide [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; September 2019.
- Micromedex Solutions [database online]. Cambridge, MA: IBM Watson Health. Updated periodically. www.micromedexsolutions.com [available with subscription]. Last Modified: April 05, 2021. Accessed April 14, 2021.

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Reference	number(s)
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4. 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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