

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 fibrillation/atrial flutter [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

A. **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.

B. **Supraventricular tachycardia**

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

C. **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 Labs; August 2023.
2. Dofetilide [package insert]. Durham, NC: Accord Healthcare, Inc.; February 2022.
3. Micromedex® [electronic version]. Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed April 1, 2024.

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).
5. Fuster V, Ryden LE, Asinger RW, et al. ACC/AHA/ESC guidelines for the management of patients with atrial fibrillation: Executive summary. A report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the European Society of Cardiology committee for practice guidelines and policy conferences (Committee to develop guidelines for the management of patients with atrial fibrillation) developed in collaboration with the North American Society of Pacing and Electrophysiology. *Circulation*. 2001;104(17):2118-50.