Dronedarone
Criteria for Use
June 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive dronedarone.

- ☐ Recently decompensated heart failure (HF) requiring hospitalization or Class IV HF
- ☐ Permanent atrial fibrillation (patients in whom normal sinus rhythm will not or cannot be restored)
- ☐ Second or third-degree atrioventricular block, or sick sinus syndrome (except in conjunction with a pacemaker)
- ☐ Significant bradycardia (e.g., less than 50 beats per minute)
- ☐ Concomitant use of a strong CYP3A inhibitor
- ☐ Concomitant use of drugs or herbal products that prolong the QT interval and may induce Torsade de Pointes
- ☐ QTc Bazett greater than or equal to 500 milliseconds with appropriate correction for prolongation of QRS interval in patients with intraventricular conduction delay and ventricular pacing
- ☐ Uncorrected hypokalemia or hypomagnesemia
- ☐ Liver or lung toxicity related to the previous use of amiodarone
- ☐ Severe hepatic impairment (i.e., Child-Pugh Grade C or baseline liver function tests greater than 2 times upper limit normal)
- ☐ Pregnancy (i.e., known pregnancy or positive pregnancy test; Category X)
- ☐ Nursing mothers

Inclusion Criteria

The answers to ALL of the following must be fulfilled in order to meet criteria.

- ☐ Restricted to VA / VA Community Care Cardiology provider or other locally designated provider for initial prescription
- ☐ Symptomatic recurrent paroxysmal or persistent atrial fibrillation documented by electrocardiogram (ECG) within the past 6 months, with a second ECG in sinus rhythm or pending cardioversion
- ☐ Intolerance (e.g., unmanageable significant adverse event), contraindication to, or ineffective therapy with at least one other antiarrhythmic agent used for the rhythm management of atrial fibrillation
- ☐ Female patients of child-bearing potential: pregnancy must be excluded prior to receiving dronedarone and patient provided counseling on use of an effective method of contraception and risks vs. benefits of taking dronedarone if patient were to become pregnant

Note: Consider discontinuation of dronedarone if the patient does not experience adequate symptom control (e.g., no or inadequate change in frequency or duration of palpitations or irregular heartbeat; no or inadequate increase in time to recurrence atrial fibrillation or flutter). Dronedarone should be discontinued in patients who develop permanent atrial fibrillation, unless cardioversion is planned. If cardioversion fails or is not planned, then dronedarone should be discontinued.