

### Clinical Pharmacy Program Guidelines for Multaq

Program	Prior Authorization
Medications	Multaq (dronedarone)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	1/2010
Pharmacy and Therapeutics Approval Date	6/2020
Effective Date	8/2020

#### 1. Background:

Multaq is an antiarrhythmic drug indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation.

Multaq carries a black box warning for increased risk of death, stroke, and heart failure in patients with decompensated heart failure or permanent atrial fibrillation. It is contraindicated in patients with symptomatic heart failure with recent decompensation requiring hospitalization or NYHA Class IV heart failure, as Multaq doubles the risk of death in these patients. Multaq is also contraindicated in patients in atrial fibrillation who will not or cannot be cardioverted into normal sinus rhythm. In patients with permanent atrial fibrillation, Multaq doubles the risk of death, stroke and hospitalization for heart failure.

Patients currently on Multaq therapy will be allowed to remain on therapy.

#### 2. Coverage Criteria:

A. **Multaq** will be approved based on one of the following:

1. All of the following criteria:

a. Diagnosis of one of the following:

(1) Paroxysmal atrial fibrillation (AF)

(2) Persistent AF defined as AF less than 6 months duration

-AND-

b. One of the following:

(1) Patient is in sinus rhythm

(2) Patient is planned to undergo cardioversion to sinus rhythm

**-AND-**

c. Patient has **none** of the following:

(1) NYHA Class IV heart failure

(2) Symptomatic heart failure with recent decompensation requiring hospitalization

**-OR-**

2. For continuation of current therapy

**Authorization will be issued for 12 months.**

### 3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

### 4. References

1. Multaq [package insert]. Ambares, France: Sanofi Winthrop Industrie. Ambares; January 2017.
2. 2014 AHA/ACC/HRS Guideline 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 Heart Rhythm Society. J Am Coll Cardiol. 2014;64(21):2246-2280.

Program	Prior Authorization – Multaq (dronedaron)
<b>Change Control</b>	
1/2010	New Policy
5/2010	Added criteria for patients failing/intolerance/ contraindication to amiodarone



Community Plan

5/2010	Changed closed ended risk factor requirement to open ended cardiovascular risk factor requirement (III. Guideline A6).
3/2011	Annual Review
3/2012	Updated criteria to include new safety warnings for patients who have permanent atrial fibrillation. Removed alternative criteria for trial and failure of amiodarone.
6/2013	Converted policy to new UHC enterprise wide formatting; Reworded requirement for permanent atrial fibrillation (see section 1 of criteria); Removed requirement that the patient has one CV risk factor; Removed prescriber requirement; Added requirement that the patient is currently receiving antithrombotic therapy; Added requirement that the patient is in normal sinus rhythm or conversion to normal sinus rhythm is planned
12/2014	Annual Review
5/2016	Updated policy template.
6/2017	Removed requirement that patient is receiving appropriate antithrombotic therapy to align with Employer and Individual's policy. Updated background and references.
6/2018	Annual review. No changes to criteria.
6/2019	Annual review with no changes.
6/2020	Annual review. Added additional clinical rules statement.