Prior Authorization Approval Criteria

**Multaq (dronedarone)**

**Generic name:** dronedarone

**Brand name:** Multaq

**Medication class:** antiarrhythmic

**FDA-approved uses:** reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors, who are in sinus rhythm or who will be cardioverted.

**Criteria for approval** (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records.
- Must have a history of paroxysmal or persistent atrial fibrillation or atrial flutter
- Must be prescribed by a cardiologist
- Must have had a recent episode of atrial fibrillation or flutter
- Must be associated with cardiovascular risk factors, such as one of the following:
  - Age > 70 years
  - Hypertension
  - Diabetes
  - Prior cerebrovascular accident
  - Left atrial diameter > 50mm
  - Left ventricular ejection fraction (LVEF) < 40
- Must be in normal sinus rhythm or will be cardioverted.
- Must have tried and failed amiodarone.
  Or
- Must be intolerant to or have a hypersensitivity to amiodarone.
  Or
- Patient is taking warfarin.

**Criteria for continuation of therapy:**
- Patient’s therapy has been re-evaluated within the last 12 months, unless a re-evaluation is not clinically appropriate for the patient’s condition at this time.
- Patient is tolerating treatment and there continues to be a medical need for the medication
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient’s condition)

**Caution:**
- Multaq doubles mortality in patients with severe or decompensated heart failure.

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
• Increases in creatinine have been reported after treatment initiation. The elevation had a rapid onset but is reversible upon discontinuation. Monitor renal function periodically.
• Hepatocellular liver injury, including acute liver failure requiring transplant, has been reported in patients treated with Multaq in the postmarketing setting.
• In women of childbearing potential, use of effective contraception is required.
• Pulmonary toxicity, such as pneumonitis or pulmonary fibrosis has been reported, and should be discontinued if it is confirmed.

Contraindication:
• Class IV heart failure or symptomatic heart failure with a recent decompensation
• Second- or third-degree atrioventricular (AV) block or sick sinus syndrome (except when used in conjunction with a functioning pacemaker)
• Bradycardia <50 bpm
• 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 interval > 500ms or PR interval > 280ms
• Severe hepatic impairment
• Liver or lung toxicity due to previous use of amiodarone.
• Patients with permanent atrial fibrillation/patients with atrial fibrillation who will not or cannot be cardioverted into normal sinus rhythm.
• In women who are pregnant, nursing, or planning to become pregnant.
• Hypersensitivity to the active substance or to any of the excipients.

Special considerations:
• Amiodarone is the most commonly used antiarrhythmic drug in patients with AF and is listed in the ACC/AHA/ESC 2010 Guidelines for the Management of Patients with Atrial Fibrillation.
• Multaq is less effective than amiodarone.

Approval Duration:
• Indefinite

Benefit Type:
• Pharmacy

Adopted: 12/09/09
Revised: 06/13/12, 12/14/16, 3/8/17
Reviewed:
3/8/17-no change