



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.
Available dosage forms:	400 mg film-coated tablets
Usual dose:	400mg twice a day
Approximate monthly cost: (based on AWP 2009)	\$259.00/month
Duration of therapy:	Indefinite

Criteria for use (*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 be prescribed by a cardiologist
 - Must have a history of paroxysmal or persistent atrial fibrillation or atrial flutter
 - 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 \geq 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.

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 \geq 500ms
- Severe hepatic impairment

Not approved if:

- Has any contraindications to the use of dronedarone
- Does not meet the above stated criteria

Special considerations:

- Amiodarone is the most commonly used antiarrhythmic drug in patients with AF and is listed in the ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation.
- Multaq is less effective than amiodarone but possibly safer due to the fact that it lacks the iodine group thereby reducing the risk of thyroid and pulmonary complications.
- Multaq doubles mortality in patients with severe or decompensated heart failure.

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 12/09/09