UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1155-10
Program	Prior Authorization/Notification
Medication	Multaq® (dronedarone)
P&T Approval Date	4/2015, 3/2016, 6/2016, 6/2017, 6/2018, 6/2019, 6/2020, 7/2021, 9/2022, 10/2023
Effective Date	1/1/2024

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]

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

1. **All** of the following criteria:

   a. Diagnosis of a history 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

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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.

4. References:

1. Multaq [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S LLC; November 2020.
2. American College of Cardiology. 2014 AHA/ACC/HRS guideline for the management of patients with atrial fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines and the Heart Rhythm Society. Circulation 2014; 130:e199.
3. American College of Cardiology. 2019 AHA/ACC/HRS Focused Update of the 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Rhythm Society. J Am CollCardiol. 2019 Jul 9;74(1):104-132.

Program	Prior Authorization/Notification - Multaq
Change Control	
Date	Change
4/2015	New program
3/2016	Annual review with no changes.
6/2016	Updated to clarify that patients already on therapy are allowed to continue prior therapy.
6/2017	Annual review. Updated reference.
6/2018	Annual review. Updated reference.
6/2019	Annual review with no changes.
6/2020	Annual review with no changes.
7/2021	Updated references.
9/2022	Annual review. Updated references, added state mandate footnote.
10/2023	Annual review. No changes.