

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 1155-12 |
| 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, 10/2024, 10/2025 |
| Effective Date | 12/1/2025 |

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:

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| <p>A. Multaq will be approved based on one of the following criteria:</p> <p>1. All of the following criteria:</p> <p>a. Diagnosis of a history of one of the following:</p> <p style="padding-left: 40px;">(1) Paroxysmal atrial fibrillation (AF) (2) Persistent AF defined as AF less than 6 months duration</p> <p style="text-align: center;">-AND-</p> <p>b. One of the following:</p> <p style="padding-left: 40px;">(1) Patient is in sinus rhythm (2) Patient is planned to undergo cardioversion to sinus rhythm</p> <p style="text-align: center;">-AND-</p> <p>c. Patient has none of the following:</p> <p style="padding-left: 40px;">(1) NYHA Class IV heart failure (2) Symptomatic heart failure with recent decompensation requiring hospitalization</p> |
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-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; May 2025.
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.
4. American College of Cardiology. 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Volume 149, Issue 1, 2 January 2024; e1-e156.

| Program | Prior Authorization/Notification - Multaq |
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| 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. |
| 10/2024 | Annual review. Updated reference. |
| 10/2025 | Annual review. Updated reference. |