PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

MULTAQ
(dronedarone)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization ***Ref # 532-A***

** Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated. OTC products are not included unless otherwise stated.*

FDA-APPROVED INDICATIONS

Multaq is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF).

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed to reduce the risk of hospitalization for atrial fibrillation in a patient with a history of paroxysmal or persistent atrial fibrillation (AF), i.e., non-permanent AF

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. Multaq is indicated to reduce the risk of hospitalization for atrial fibrillation in patients in sinus rhythm with a history of paroxysmal or persistent atrial fibrillation (AF).[1]

In patients with permanent atrial fibrillation, Multaq doubles the risk of death, stroke and hospitalization for heart failure. Multaq offers no benefit in subjects in permanent AF and is contraindicated in these patients.[1-4]

REFERENCES

1. Multaq [package insert]. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; November 2020.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2021; Accessed March 11, 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: https://www.micromedexsolutions.com. Accessed March 11, 2021.
4. Multaq (dronedarone) Drug Safety Communication. https://www.fda.gov/drugs/drugsafety/ucm283933.htm. Accessed March 2021.

Written by:	UM Development (NB)
Date Written:	08/2010
Revised:	(TM) 08/2011, 12/2011, 08/2012, 09/2012 (updated PI, question 1), 09/2013, 05/2014 (SF) 04/2015; (KM) 04/2016 (removed sinus rhythm and monitoring question), 09/2016 (updated wording of criteria for approval to not discriminate for TGC patients); (CT) 04/2017; (KM) 04/2018 (no clinical changes); (DFW) 04/2019 (removed MDC designation from title/document), 04/2020 (no clinical changes), 04/2021 (no clinical changes)
Reviewed:	Medical Affairs 08/2010, (KP) 08/2011, (KP) 01/2012; (LS) 08/2012, (LS) 09/2012, 10/2012; (DC) 09/2013; (LS) 05/2014; (LCB) 04/2015; (ME) 08/2016; (AN) 04/2017; (GAD) 04/2019, CHART 04/30/20, (CHART) 04/22/2021 External Review: 12/2010, 01/2012, 02/2012, 12/2012, 12/2013, 08/2014, 08/2015, 08/2016, 10/2016, 08/2017, 08/2018, 08/2019, 08/2020, 08/2021

CRITERIA FOR APPROVAL

1	Is the requested drug being prescribed to reduce the risk of hospitalization for atrial fibrillation in a patient with a history of paroxysmal or persistent atrial fibrillation (AF), i.e., non-permanent AF?	Yes	No

Mapping Instructions			
	Yes	**No**	**DENIAL REASONS – DO NOT USE FOR MEDICARE PART D**
1.	Approve, 12 months	Deny	You do not meet the requirements of your plan. Your plan covers this drug when you have a history of atrial fibrillation (AF) that is not permanent. Your request has been denied based on the information we have. [Short Description: No approvable diagnosis]