

## Commercial/Healthcare Exchange Step Criteria

Effective: September 2010

**Step Therapy Name:** ACE-ARB Inhibitors

**Step 1 Agent(s):** benazepril/HCT, captopril/HCT, enalapril/HCT, fosinopril/HCT, lisinopril/HCT, quinapril/HCT, ramipril, trandolapril, losartan/HCT, candesartan/HCT, irbesartan/HCT, Olmesartan/HCT

**Step 2 Agent(s)\*:** Edarbi, Edarbyclor, Tekturna, Tekturna HCT

\*Must try TWO (2) Step 1 Agents

**Medication/Class Description:**

Angiotensin II is formed from angiotensin I in a reaction catalyzed by angiotensin-converting enzymes (ACE, kinase II). Angiotensin II is the principal pressor agent of the renin-angiotensin system, with effects that include vasoconstriction, stimulation of synthesis and release of aldosterone, cardiac stimulation, and renal reabsorption of sodium. Azilsartan medoxomil is an orally administered prodrug that is rapidly converted by esterases during absorption to the active moiety, azilsartan. Azilsartan blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. Its action is, therefore, independent of the pathway for angiotensin II synthesis.

**Required Medical Information:**

1. Diagnosis
2. Previous medications tried/failed
3. Current blood pressure reading

**Age Restrictions:**

Tekturna, Tekturna HCT: 6 years of age and older  
Edarbi, Edarbyclor: 18 years of age and older

**Prescriber Restrictions:** N/A

**Coverage Duration:** 12 Months

**Exceptions for Stepped Medications:**

- A. Patient has had a trial and failure of TWO Step 1 Agents, defined as
  - a. Failure to decrease/control blood pressure; **OR**
- B. Patient has an intolerance or contraindication to TWO Step 1 Agents, defined as (but not limited to):
  - a. Allergic reaction; **OR**
  - b. Adverse drug reactions.

**References:**

1. EDARBYCLOR oral tablets, azilsartan medoxomil and chlorthalidone oral tablets. Takeda Pharmaceuticals America, Inc (Per Manufacturer), Deerfield, IL, 2011
2. Edarbi oral tablets, azilsartan medoxomil oral tablets. Takeda Pharmaceuticals America, Inc., Deerfield, IL, 2011
3. TEKTURNA(R) oral tablets, pellets, aliskiren oral tablets, pellets. Noden Pharma USA Inc (per FDA), Boston, MA, 2017.

**Policy Revision history**

<b>Rev #</b>	<b>Type of Change</b>	<b>Summary of Change</b>	<b>Sections Affected</b>	<b>Date</b>
1	New Policy	New Policy	All	9/2010
2	Update	Moved to updated template Updated age restrictions	All	2/2020