



**Medication Policy Manual**

**Policy No:** dru468

**Topic:** High Cost Blood Pressure Medications

**Date of Origin:** November 11, 2016

**Committee Approval Date:** July 14, 2017

**Next Review Date:** April 2018

**Effective Date:** August 1, 2017

### **IMPORTANT REMINDER**

This Medication Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of Medication Policy is to provide a guide to coverage. Medication Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

### **Description**

Angiotensin receptor blocker- (ARB), angiotensin converting enzyme inhibitor- (ACE), and beta blocker-containing medications are used for the treatment of high blood pressure. There are numerous medications available in these classes of medications and many are available generically.

## Policy/Criteria

- I. Most contracts require prior authorization approval of certain high cost blood pressure medications prior to coverage. High cost blood pressure medications may be considered medically necessary when criterion A or B below is met.
- A. High cost blood pressure medications included in **Table 1** below may be considered medically necessary when there is an intolerance or contraindication to an **inactive** ingredient in the AB-rated generic.

**Table 1. High cost blood pressure medications with AB-rated generics**

Branded Product	AB-rated Generic	Branded Product	AB-rated Generic
<b>Accupril</b>	quinapril	<b>Hyzaar</b>	losartan/ HCTZ
<b>Accuretic</b>	quinapril/ HCTZ	<b>Inderal LA</b>	propranolol extended release
<b>Aceon</b>	perindopril	<b>Lopressor HCT</b>	metoprolol/ HCTZ
<b>Altace</b>	ramipril	<b>Lotensin</b>	benazepril
<b>Atacand</b>	candesartan	<b>Lotensin HCT</b>	benazepril/ HCTZ
<b>Atacand HCT</b>	candesartan/ HCTZ	<b>Lotrel</b>	amlodipine/ benazepril
<b>Avalide</b>	irbesartan/ HCTZ	<b>Mavik</b>	trandolapril
<b>Avapro</b>	irbesartan	<b>Micardis</b>	telmisartan
<b>Azor</b>	amlodipine/ olmesartan	<b>Micardis HCT</b>	telmisartan/ HCTZ
<b>Benicar</b>	olmesartan	<b>Tarka</b>	trandolapril/ verapamil ER
<b>Benicar HCT</b>	olmesartan/ HCTZ	<b>Tenoretic</b>	atenolol/ chlorthalidone
<b>Corzide</b>	nadolol/ bendroflumethiazide	<b>Tribenzor</b>	olmesartan/ amlodipine/ HCTZ
<b>Cozaar</b>	losartan	<b>Twynsta</b>	telmisartan/ amlodipine
<b>Diovan</b>	valsartan	<b>Vasotec</b>	enalapril
<b>Diovan HCT</b>	valsartan/ HCTZ	<b>Zestoretic</b>	lisinopril/ HCTZ
<b>Exforge</b>	amlodipine/ valsartan	<b>Zestril</b>	lisinopril
<b>Exforge HCT</b>	amlodipine/ valsartan/ HCTZ	<b>Ziac</b>	bisoprolol/ HCTZ

**OR**

- B.** High cost blood pressure medications included in **Table 3** below may be considered medically necessary when two generic blood pressure medications plus one alternative specified in Table 3 is ineffective or not tolerated.

**Table 3. High cost blood pressure medications with comparable alternatives**

<b>High cost blood pressure medication</b>	<b>Alternative(s)</b>
Byvalson	bystolic (nebivolol), valsartan
Clorpres	chlorthalidone, clonidine
Dutoprol Extended Release	metoprolol, HCTZ
Edarbi	irbesartan, losartan, valsartan, olmesartan
Edarbyclor	valsartan/ HCTZ, irbesartan/ HCTZ , losartan/ HCTZ
Inderal XL	propranolol HCL ER
InnoPran XL	propranolol HCL ER
Prestalia	perindopril, amlodipine
Tekturna	irbesartan, losartan, valsartan, olmesartan
Tekturna HCT	valsartan/ HCTZ, irbesartan/ HCTZ , losartan/ HCTZ

**II. Administration, Quantity Limitations, and Authorization Period**

- A.** OmedaRx considers the medications in this policy to be a self-administered.
- B.** Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

**Position Statement**

- The intent of the policy is to allow coverage of high cost blood pressure medications when lower cost blood pressure medications are not effective, not tolerated, or are contraindicated.
- Numerous single-entity and combination treatments are available generically in the ARB, ACE-inhibitor, and beta-blocker classes of blood pressure medications.
- Brand or high cost generic medications have not been proven to be safer or more effective than lower cost generics.

- As a class, the ARBs are similar to the ACEIs with regard to blood pressure lowering and in reducing morbidity/mortality in specific subpopulations (e.g. preventing progression of kidney disease in diabetic patients, preventing recurrent stroke, and decreasing the risk of cardiovascular morbidity and mortality).
- Combining an ARB with an ACEI results in little additional blood pressure lowering; however, it increases the risk of adverse effects such as hyperkalemia.
- The combination of aliskiren, a direct renin inhibitor, with an ARB or an ACEI may increase the risk of non-fatal stroke and end-stage renal disease in some patients with type 2 diabetes. Concomitant use of these medications is not recommended.
- Beta-blockers are not commonly used for initial therapy of high blood pressure in the absence of a specific indication for their use.

### *Clinical Efficacy*

- The angiotensin converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), aliskiren, and beta blockers are all used in the treatment of hypertension. [1]
- Reduction in cardiovascular morbidity and mortality, prevention of recurrent strokes, and prevention of progression of kidney disease are not unique to any ARB or ACEI and have been demonstrated with many of the available products. [2,3]
- No single ARB or ACEI has been shown to be better than another with regard to improving long- term outcomes (none of the outcomes studies compare one ARB versus another).
- The 2014 Eighth Joint National Committee (JNC8) treatment guidelines recommend initial treatment of hypertension with either a thiazide diuretic, calcium channel blocker, ACEI, or ARB. No distinction is made between products. [4]
- There is no high quality evidence to show that combining an ARB and an ACEI is superior to either one alone with regard to improving long-term outcomes.
  - \* A single high quality study (ONTARGET study) concluded that there was no difference between telmisartan or ramipril, or the combination of each for the composite endpoint death from cardiovascular causes, myocardial infarction, or stroke. [5]
  - \* Three additional studies with combination ACEI and ARB arms were appraised as being of low quality because of high discontinuation rates and confounding medications. [5-8]
- There is currently no evidence that aliskiren, a direct renin inhibitor, has a beneficial impact on long-term clinical outcomes.
- A study combining aliskiren with an ACEI or an ARB in patients with type 2 diabetes and renal impairment was terminated due to an increased incidence of non-fatal stroke, renal complications, hyperkalemia, and hypotension after 18 to 24 months. [9]  
Concomitant administration of aliskiren with ACEIs and ARBs is not recommended.

- Beta-blockers are not recommended for the initial treatment of hypertension in the absence of a specific indication for their use (such as given post-acute myocardial infarction and to stable patients with heart failure or asymptomatic left ventricular dysfunction) since they may have an adverse effect on some cardiovascular outcomes. [10]

*Safety*

- Both ARBs and aliskiren (along with ACEIs) carry a boxed warning regarding use in pregnancy (all can cause injury and even death to a developing fetus). Beta-blockers carry a boxed warning regarding abrupt discontinuation of therapy which have caused exacerbations of angina pectoris and myocardial infarction. [1]
- Adverse effects reported with ACEIs, ARBs, and aliskiren include dizziness, fatigue, hypotension, diarrhea, dry cough, and elevated serum potassium. Adverse effects reported with beta-blockers include diarrhea, vomiting, dizziness, hypertension, sleep disorder, and fatigue. [1]
- The incidence of dry cough with ACEIs ranges from 7% to 15%; whereas the reported incidence with ARBs is generally around 1% (similar to placebo). [1]

Cross References
None

Codes	Number	Description
N/A		

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*Revision History*

<b>Revision Date</b>	<b>Revision Summary</b>
07/14/2017	Removed the following medications from the policy: generic products, Epaned, and Qbreliis (effective 08/01/2017)
03/10/2017	No criteria changes with this annual update
11/11/2016	New policy effective 1/1/2017.