



## Prior Authorization Approval Criteria

### *Tekturna (aliskiren)*

<b>Generic name:</b>	aliskiren
<b>Brand name:</b>	Tekturna
<b>Medication class:</b>	Direct renin inhibitor
<b>FDA approved uses:</b>	Treatment of hypertension. May be used alone or in combination with other antihypertensive agents.
<b>Available dosage forms:</b>	150 mg and 300 mg tablets
<b>Usual dose:</b>	150 mg – 300 mg once daily
<b>Duration of therapy:</b>	Indefinite

**Criteria for use:** *(bullet points below are all inclusive unless otherwise noted):*

- Clinically diagnosed mild to moderate hypertension.
- Failed/intolerant to 1 formulary ACE inhibitor and 1 formulary ARB

**Cautions:**

- Experience with the use of aliskiren in patients with severe renal impairment is limited and therefore, caution is warranted
- Drug interactions:
  - Irbesartan (Avapro): 50% reduction in aliskiren concentrations
  - Atorvastatin (Lipitor): 50% increase in aliskiren concentrations
  - Ketoconazole (Nizoral): 80% increase in aliskiren concentrations
  - Furosemide (Lasix): reduced blood concentration levels of furosemide

**Contraindications:**

- None reported at this time.

**Not approved if:**

- Does not meet the above stated criteria

**Special considerations:**

Until more data are available, older hypertensives should be considered first.

*Adverse effects:*

- A concern is hypotension that is not reversed when the drug is stopped due to the strong binding of renin and the long half life of aliskiren (24-30 hrs).
- Aliskiren still is detectable in the kidneys up to 3 weeks after discontinuation.
- Doses greater than 300 mg did not give an increased blood pressure response but increased the rate of diarrhea.
- Rate of cough was 1.1%, which was about one-half to one-third the rate of cough seen with ACE inhibitors.
- Two cases of angioedema with respiratory symptoms and two cases of periorbital edema without respiratory symptoms were noted. Therefore angioedema occurred in 0.06% of patients.
- Increases in potassium were uncommon (0.9% compared with 0.6% with placebo). However the rate of hyperkalemia is expected to be greater if aliskiren is combined with an ACE inhibitor.

*Cautions:*

- Experience with the use of aliskiren in patients with severe renal impairment is limited and therefore, caution is warranted. It does not appear to have an effect on serum creatinine, but data is lacking to confirm this.

*Indications:*

- The majority of trials included patients with mild to moderate hypertension.
- Limited data suggest that aliskiren also could be safe in severe hypertension as part of a combination therapy strategy.

*Efficacy:*

- Overall data from studies show aliskiren to be superior to placebo and similar or better efficacy compared with other commonly used agents.
- Aliskiren directly inhibits rennin while other antihypertensives target the renin-angiotensin system.
- Has not been studied with maximal dose of ACE inhibitors.
- Modestly lowers blood pressure when used as monotherapy and has shown to have additive effects when combined with a thiazide diuretic or an ARB.
- Aliskiren has not been shown to improve clinical outcomes as seen with ACE inhibitors and ARB's in heart failure, coronary artery disease and renal disease therefore should only be used for hypertension at this time

**Drugs that block RAAS (Medical Letter, 04/09/2007):**

DRUG	STRENGTHS	DOSAGE	COST <sup>1</sup>
<b>ACE INHIBITORS</b>			
Benazepril – generic	5, 10, 20, 40 mg	10-80 mg in	\$25.50
Lotensin	tabs	1 or 2 doses	41.70
Captopril – generic	12.5, 25, 50,	12.5-150 mg in	18.90 <sup>2</sup>
Captoten	100 mg tabs	2 or 3 doses	51.00 <sup>2</sup>
Enalapril – generic	2.5, 5, 10, 20 mg	2.5-40 mg in	19.80
Vasotec	tabs	1-2 doses	34.50
Fosinopril – generic	10, 20, 40 mg	10-80 mg in	27.00
Monopril	tabs	1 or 2 doses	41.40
Lisinopril – generic	2.5, 5, 10, 20,	5-40 mg	24.30
Prinivil	30, 40 mg tabs	once	30.30
Zestril			37.80
Moexipril – generic	7.5, 15 mg tabs	7.5-30 mg in	35.70
Univas		1 or 2 doses	42.90
Perindopril – Aceon	2, 4, 8 mg tabs	4-8 mg in	52.20
		1 or 2 doses	
Quinapril – generic	5, 10, 20, 40 mg	5-80 mg in	29.70
Accupril	tabs	1 or 2 doses	44.70
Ramipril – Altace	1.25, 2.5, 5,	1.25-20 mg in	39.90
	10 mg caps	1 or 2 doses	
Trandolapril – generic	1, 2, 4 mg tabs	1-8 mg in	32.10
Mavik		1 or 2 doses	38.40
<b>ARBs</b>			
Candesartan – Atacand	4, 8, 16, 32 mg	8-32 mg once	53.40
	Tabs		
Eprosartan – Teveten	400, 600 mg	400-800 mg in	62.10
	tabs	1 or 2 doses	
Irbesartan – Avapro	75, 150, 300 mg	150-300 mg once	54.30
	Tabs		
Losartan – Cozaar	25, 50, 100 mg	25-100 mg in	54.30
	tabs	1 or 2 doses	
Olmesartan – Benicar	5, 20, 40 mg	20-40 mg once	48.90
	Tabs		
Telmisartan – Micardis	20, 40, 80 mg	40-80 mg once	56.10
	Tabs		
Valsartan – Diovan	40, 80, 160,	80-320 mg once	59.70
	320 mg tabs		
<b>RENIN INHIBITOR</b>			
Aliskiren – Tekturna	150, 300 mg tabs	150-300 mg once	79.99 <sup>3</sup>

1. Cost for 30 days' treatment with the lowest daily dosage, according to the most recent data (February 28, 2007) from retail pharmacies nationwide available from Wolters Kluwer Health.

2. Cost based on purchase of 30 12.5 mg tablets.

3. Retail cost at one Walgreens pharmacy.

P&T Approval: \_\_\_\_\_ Date: \_\_\_\_\_  
 Adopted: 9/12/07