



Prior Authorization Approval Criteria

Tekamlo (aliskiren and amlodipine)

Generic name:	aliskiren and amlodipine
Brand name:	Tekamlo
Medication class:	direct renin inhibitor and calcium channel blocker
FDA-approved uses:	Treatment of hypertension
Available dosage forms:	Tablets (mg aliskiren / mg amlodipine): 150/5, 150/10, 300/5, 300/10
Usual dose range:	One tablet daily (150mg/5mg to 300mg/10mg)
Duration of therapy:	Indefinite
Approximate monthly cost: (Based on AWP 2011)	150/5mg daily = \$89.28 150/10mg daily = \$89.28 300/5mg daily = \$112.68 300/10mg daily = \$112.68

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

- The indicated diagnosis (including any applicable labs and /or tests) and medication usage must be supported by documentation from the patient's medical records.
- Clinically diagnosed mild to moderate hypertension
- Failed / intolerant to thiazide diuretics
- Failed / intolerant to ace inhibitors
- Failed ARBs
- Failed/ intolerant to beta blockers
- Failed calcium channel blockers
- Must have tried and failed two drug combinations

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
- This fixed dose combination is being used for initial therapy

Special Considerations:

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 300mg 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 rennin-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

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

FCHP Pharmacy and Therapeutics Committee approval: _____

Date: _____

Adopted: 3/09/11