

Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

Therapeutic Class:

Direct Renin Inhibitors

Overview:

Aliskiren (Tekturna[®]) is a novel agent for the treatment of essential hypertension and, like angiotensin converting enzyme inhibitors and angiotensin receptor blockers, exerts its activity on the renin-angiotensin system. Aliskiren is a potent, direct inhibitor of renin. Renin facilitates the conversion of angiotensinogen to angiotensin I, which is subsequently cleaved by angiotensin-converting enzyme to form angiotensin II, a potent vasoconstrictor. Therefore, aliskiren prevents the ultimate formation of angiotensin II, thus causing a reduction in blood pressure. At this time, it is not known, whether aliskiren affects any other step in the cascade.

Aliskiren is available as 150- and 300-mg tablets for once-daily administration. Although the usual dose is 150 mg once daily, the dose may be titrated to 300 mg daily for patients who do not respond to the lower dose. Aliskiren may be administered without regard to food; however, aliskiren should be taken consistently, since high-fat meals can result in a significant decrease in absorption. Common adverse effects associated with the use of aliskiren include diarrhea, cough, headache, nasopharyngitis, and dizziness.

As with other medications that exert their action on the renin-angiotensin-aldosterone system, aliskiren has a black box warning regarding its use in pregnancy. Aliskiren can lead to injury and possibly death of the developing fetus when administered during pregnancy. Therefore, this medication should not be administered to pregnant women.

Generic Name	Brand Name	Manufacturer
Aliskiren	Tekturna [®]	Novartis Pharmaceuticals

Summary: Aliskiren, a novel antihypertensive, has produced blood pressure reductions comparable with other agents that exert their activity on the renin-angiotensin system (eg, ACEIs). It has also shown increased blood pressure-lowering effects in combination with these agents. At this time, it is unknown whether aliskiren has an effect on outcome measures such as heart attack, stroke, or nephropathy. Common adverse effects associated with aliskiren include dizziness, headache, and diarrhea. Aliskiren is the only medication in this new class, thus, offers a new mechanism by which to target control of blood pressure.