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## **Indiana Medicaid Therapeutics Committee** **Therapeutic Class Review Summary**

### **Therapeutic Class:**

Direct Renin Inhibitor-Angiotensin Receptor Blocker Combination Product

### **Overview:**

Valturna (aliskiren/valsartan) is a combination product indicated for the treatment of hypertension in patients not adequately controlled on monotherapy. It is also indicated for use as initial therapy in patients likely to need multiple drugs to achieve their blood pressure goals. Valturna contains the potent direct renin inhibitor aliskiren as well as the angiotensin receptor blocker valsartan. Like angiotensin converting enzyme inhibitors and angiotensin receptor blockers, aliskiren exerts its activity on the renin-angiotensin system. 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. Whether aliskiren affects any other step in the cascade is unknown. In addition, valsartan inhibits the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT<sub>1</sub> receptor in many tissues.

Valturna is approved for once-daily administration and is available in the tablet strengths 150/160 mg and 300/320 mg. Antihypertensive effects are usually seen within two weeks; however, the dose may be titrated up to a maximum of 300/320 mg if blood pressure remains uncontrolled after two to four weeks of therapy. Because high-fat meals decrease aliskiren absorption substantially, patients should establish a routine pattern for taking Valturna with regard to meals. Common adverse effects associated with the use of Valturna include the following: fatigue, nasopharyngitis, diarrhea, upper respiratory tract infection, urinary tract infection, influenza, and vertigo.

As with other medications that act directly on the renin-angiotensin system, the Valturna label contains a boxed warning regarding its use in pregnancy. Specifically, drugs affecting the renin-angiotensin system can cause injury and possibly death to a developing fetus when administered during pregnancy. Therefore, these products should not be given to pregnant women and Valturna should be discontinued as soon as possible when pregnancy is detected.

<b>Generic Name</b>	<b>Brand Name</b>	<b>Manufacturer</b>
Aliskiren/Valsartan	Valturna	Novartis Pharmaceuticals



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**Indiana Medicaid Therapeutics Committee**  
*Therapeutics Class Review Summary of*  
*Direct Renin Inhibitor-Angiotensin Receptor Blockers*

**Summary:**

Valturna is a new combination product that contains aliskiren, a potent direct renin inhibitor, and valsartan, an angiotensin receptor blocker. Though aliskiren and valsartan are effective in lowering blood pressure individually, Valturna has been shown to produce blood pressure reductions superior to aliskiren or valsartan monotherapy. PDL inclusion of antihypertensives should be based on clinical trials regarding the safety and efficacy of combination products as well as their individual components.