

What's new...What's next...What to do now

DRUG APPROVAL

Tekturna[®] (aliskiren)*

- Tekturna (Novartis Pharmaceuticals, Inc.), formerly known as Rasilez, received approval by the U.S. Food and Drug Administration (FDA) for the treatment of hypertension (high blood pressure) on March 6, 2007.
- Tekturna, a renin inhibitor, is the first medication of this class to be approved by the FDA.
- This product is administered once daily and may be used alone or in combination with other high blood pressure medications.
- Tekturna was effective in clinical trials across all populations studied; however, African American patients tended to have smaller reductions in blood pressure than Caucasians and Asians.

Mechanism of Action

- Tekturna inhibits renin, a kidney enzyme involved in the regulation of blood pressure.
- Other available high blood pressure medications that act on the renin-angiotensin system are angiotensin-converting enzyme (ACE) inhibitors and angiotensin II receptor blockers (ARBs).

Adverse Effects

- The most common side effect experienced by patients taking Tekturna in clinical trials was diarrhea.
- Rarely, patients taking Tekturna developed an allergic reaction with swelling of the face, lips or tongue and difficulty breathing, as has been seen with other high blood pressure medications that act directly on the renin-angiotensin system.

Available Strengths

- Tablet(s); 150 mg and 300 mg

Anticipated Launch Date[†]

- March 2007

BACKGROUND

- About 65 million American adults – nearly one in three – have high blood pressure.
- Over half of all Americans aged 60 years and over have high blood pressure.
- High blood pressure increases the risk of stroke, heart attack, kidney failure, heart failure and death.
- According to the National Institutes of Health, high blood pressure and its complications cost the U.S. economy over \$100 billion each year.

BUDGET IMPACT

- Caremark estimates Tekturna will increase pharmacy budgets by between \$0.02 and \$0.06 Per Member Per Month, which equates to \$0.30 to \$0.67 Per Member Per Year, during its first year on the market.
- Caremark will continue to monitor the long-term budget effects of Tekturna's introduction into the pharmaceutical marketplace.

CAREMARK RESPONSE

- Caremark recognizes the unique needs of plan participants with hypertension.
- Tekturna's place in therapy has yet to be determined.
- Tekturna will be considered for inclusion in the URPlus program. URPlus is a retrospective utilization review program that utilizes medical and pharmacy claims.
- Plan participants requiring Tekturna may be good candidates for the AccordantCare[®] Health Management Program for hypertension. This disease management program helps plan participants with hypertension better manage their condition, including reinforcing the importance of medication compliance, leading to overall decreased healthcare costs and improved outcomes.
- Caremark will continue to monitor Tekturna to determine if any additional clinical programs are needed.
- For more information call your Caremark account representative.

Please Note: This document provides a brief overview of the subject. This review is provided as a reference only, and is based in part on information derived from third parties.

* This information is current as of March 6, 2007

† This Launch Date may not reflect the date of availability for this medication. Due to circumstances beyond the control of Caremark, information related to prospective medication launch dates is subject to change without notice. This information should not be solely relied upon for decision-making purposes. This medication is expected to be available in pharmacies within a few days of this date.

References

- Caremark Internal Pharmacy Budget Impact, Research and Development.
- FDA News. *FDA approves new drug treatment for high blood pressure*. Food and Drug Administration Web site. Available at: <http://www.fda.gov/bbs/topics/NEWS/2007/NEW01580.html>. Accessed March 6, 2007.
- *High blood pressure in the United States*. Bethesda, MD: National Institutes of Health; National Heart, Lung, and Blood Institute; 2006. Available at: <http://hp2010.nhlbi.nih.gov/mission/about/bp/about/bp.htm>. Accessed March 6, 2007.
- Tekturna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; March 2007.
- *What is high blood pressure?* Bethesda, MD: National Institutes of Health, National Heart, Lung, and Blood Institute; April 2006. Available at: http://www.nhlbi.nih.gov/health/dci/Diseases/Hbp/HBP_Whats.html. Accessed March 6, 2007.