

Pharmacy Policy Bulletin

Title: Oral Antihypertensive Agents

Policy #: Rx.01.65

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

▸ Intent:

N/A

▸ Description:

N/A

▸ Policy:

Avapro®/Avalide ; Atacand®/Atacand HCT®; Micardis®/Micardis HCT® ; Teveten/Teveten HCT ; Exforge®/ Exforge HCT® ;Twynsta®;Tekturna /Tekturna HCT® ;Tekamlo; Amturnide ; Valturna or Edarbi/Edarbyclor is approved when the following inclusion criteria is met:

- Documentation of a trial and failure of two of the following:
 - o A generic angiotensin receptor blocker containing product (e.g .losartan)
 - o A Diovan/Diovan HCT containing product
 - o A Benicar/Benicar HCT containing product

Brand ARB/ARB combos with generic equivalents (e.g. Teveten) are approved when the following inclusion criteria is met:

- Documentation of a trial of the generic equivalent

▸ Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Atacand [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2009. Also available online at: http://www.atacand.com/50693_51024.aspx?mid=18. Accessed December 30, 2011.

Avapro [package insert]. New York, NY: Bristol-Myers Squibb Sanofi-Synthelabo Partnership; 2007. Also available online at: <http://www.avapro.com>. Accessed December 30, 2011.

Chobanian AV, Bakris GL, Black HR, et al. Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Seventh report of the Joint National Committee on prevention, detection, evaluation, and treatment of high blood pressure. *Hypertension*. 2003;42(6):1206-1252.

Cozaar [package insert]. Whitehouse Station, NJ: Merck; 2009. Also available online at: http://www.cozaar.com/losartan_potassium/cozaar/hcp/index.jsp. Accessed December 30, 2011.

Exforge® (amlodipine and valsartan) [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corp; 2009.

Exforge HCT® (amlodipine, valsartan, and hydrochlorothiazide) [prescribing information]. East Hanover, NJ: Novartis Pharmaceutical Corp; 2009.

Exforge® (amlodipine and valsartan). In: Drugdex [online through Micromedex Healthcare Series]. Greenwood Village, CO: Thomson Micromedex. Accessed December 30, 2011.

Facts & Comparisons. Amlodipine. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed December 30, 2011.

Facts & Comparisons. Angiotensin II receptor blockers. [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com/efacts.asp> [via subscription only]. Accessed December 30, 2011.

Facts & Comparisons. Exforge® (amlodipine and valsartan). [Facts & Comparisons Web site]. Available at: <http://www.factsandcomparisons.com> [via subscription only]. Accessed December 30, 2011.

Facts and Comparisons website [Valturna]. Available at www.factsandcomparisons.com. Accessed December 30, 2011.

Gradman AH, Schmieder RE, Lins RL, et al. Aliskiren, a novel orally effective renin inhibitor, provides dose- dependent antihypertensive efficacy and placebo-like tolerability in hypertensive patients. *Circulation*. 2005;111(8):1012-1018.

Joint National Committee (JNC). JNC VII guidelines for the treatment of hypertension. [National Heart, Lung, and Blood Institute (NHLBI) Web site]. Available at: <http://www.nhlbi.nih.gov>. Accessed December 30, 2011.

Micardis [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals; 2009. Also available online at: <http://www.micardis.com/>. Accessed December 30, 2011.

Micromedex. Amlodipine. [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed December 30, 2011.

Micromedex. Tekturna. [Micromedex Web site]. Available at: <http://www.micromedex.com> [via subscription only]. Accessed December 30, 2011.

Micromedex website [Valturna]. Available at www.micromedex.com. Accessed December 30, 2011.

Oparil S, Patel S, Fang H, et al. Aliskiren and Valsartan in Stage 2 hypertension: subgroup analysis of a randomized, double blind study. *Adv Ther* 2008; 25(12): 1288-1302.

Oparil S, Yarows SA, Patel S, et al. Efficacy and safety of combined use of aliskiren and valsartan in patients with hypertension: A randomised, double-blind trial. *Lancet*. 2007;370(9583):221-229.

Pool JL, Schmieder RE, Azizi M, et al. Aliskiren, an orally effective renin inhibitor, provides antihypertensive efficacy alone and in combination with valsartan. *Am J Hypertens*. 2007;20(1):11-20.

Product Information: TWYNSTA(R) oral tablets, telmisartan amlodipine oral tablets. Boehringer Ingelheim Pharmaceuticals Inc., Ridgefield, CT, 2009.

Stanton A, Jensen C, Nussberger J, O'Brien E. Blood pressure lowering in essential hypertension with an oral renin inhibitor, aliskiren. *Hypertension*. 2003;42(6):1137-1143.

Strasser RH, Puig JG, Farsang C, et al. A comparison of the tolerability of the direct renin inhibitor aliskiren and lisinopril in patients with severe hypertension (Abstract). *J Hum Hypertens*. 2007;21(10):780-787.

Tekturna [package insert]. East Hanover, NJ: Novartis Pharmaceuticals; 2010.

Telmisartan/amlodipine [product information]. Micromedex Healthcare. Greenwood Village, CO: Thomson MICROMEDEX. Accessed December 30, 2011.

Teveten [package insert]. Cranbury, NJ: Kos Pharmaceuticals; 2008. Also available online at: <http://www.rxabbott.com/pdf/tevetenhct.pdf>. Accessed December 30, 2011.

Valturna [package insert]. Novartis Pharmaceuticals. East Hanover NJ; 2010.


Villamil A, Chrysant SG, Calhoun D, et al. Renin inhibition with aliskiren provides additive antihypertensive efficacy when used in combination with hydrochlorothiazide. *J Hypertens*. 2007;25(1):217-226.

Facts and Comparisons website [Tekamlo]. Available at www.factsandcomparisons.com. Accessed December 30, 2011

Facts and Comparisons website [Edarbi]. Available at www.factsandcomparisons.com. Accessed December 30, 2011

Edarbyclor [package insert] Deerfield IL. Takeda Pharmaceuticals 2011.

Applicable Drugs:

 Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Valturna	aliskiren/valsartan
Avapro	irbesartan
Avalide	irbesartan/HCT
Atacand	candesartan
Atacand HCT	candesartan/HCT
Cozaar	losartan
Hyzaar	losartan/HCT
Micardis	telmisartan
Micardis HCT	telmisartan/HCT
Teveten	eprosartan
Teveten HCT	eprosartan/HCT
Exforge	amlodipine besylate/valsartan
Exforge HCT	amlodipine besylate/valsartan/hydrochlorothiazide
Twynsta	amlodipine besylate/telmisartan

Tekturna	aliskiren
Tekturna HCT	aliskiren HCT
Tekamlo	Aliskiren/amlodipine
Amturnide	Aliskiren, amlodipine and hydrochlorothiazide
Edarbi	Azilsartan
Edarbyclor	azilsartan medoxomil and chlorthalidone

 **Cross References:**

Policy Version Number: 1.00
P&T Approval Date: March 08, 2012
Policy Effective Date: June 01, 2012
Next Required Review Date: March 08, 2013

The Policy Bulletins on this web site were developed to assist Independence Blue Cross ("IBC") in administering the provisions of the respective benefit programs, and do not constitute a contract. If you are an IBC member, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. IBC does not provide health care services, medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of IBC. If you have a specific medical condition, please consult with your doctor. IBC reserves the right at any time to change or update its Policy Bulletins. © 2012 Independence Blue Cross. All Rights Reserved.

Independence Blue Cross is an independent licensee of the Blue Cross and Blue shield Association