

Medical Policy



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Blue Cross Blue Shield Association

Title: Antihypertensive Medications

➤ Prime Therapeutics will review Prior Authorization requests

Prior Authorization Form:

<https://www.bcbsks.com/CustomerService/Forms/pdf/PriorAuth-6058KS-ST.pdf>

Link to Drug List (Formulary):

http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.shtml

Professional

Original Effective Date: January 1, 2008
Revision Date(s): April 1, 2010;
May 20, 2011; July 1, 2012;
January 1, 2013; September 1, 2013;
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December 1, 2016; November 1, 2017
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Institutional

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May 20, 2011; July 1, 2012;
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October 1, 2015; October 1, 2015;
September 1, 2016; October 1, 2016;
December 1, 2016; November 1, 2017
Current Effective Date: November 1, 2017

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DESCRIPTION

The intent of the Antihypertensive Medication Prior Authorization program is to encourage use of cost-effective generic products - ACEIs, ACEI combinations (ACEI/diuretics or ACEI/calcium channel blockers [CCBs]), ARBs, or ARB combinations - over the more expensive brand ARBs, brand ARB combinations, brand renin inhibitors and renin inhibitor combinations (renin inhibitor/diuretic, renin inhibitor/ARB, or renin inhibitor/CCB). This program will accommodate for use of brand products when generic prerequisites cannot be used due to previous trial and failure, documented intolerance, FDA labeled contraindication, or hypersensitivity. Requests for brand ARB or renin inhibitor products will be reviewed when patient-specific documentation is provided.

Target Agents

| Angiotensin II Receptor Antagonists (ARBs), Combinations | |
|---|---|
| Brand | Generic |
| Atacand® | candesartan ^a |
| Atacand HCT® | candesartan/HCTZ ^{ab} |
| Avalide® | irbesartan/HCTZ ^{ab} |
| Avapro® | irbesartan ^a |
| Azor® | olmesartan/amlodipine ^a |
| Benicar® | olmesartan ^a |
| Benicar HCT® | olmesartan/HCTZ ^{ab} |
| Byvalson™ | nebivolol/valsartan |
| Cozaar® | losartan ^a |
| Diovan® | valsartan ^a |
| Diovan HCT® | valsartan/HCTZ ^{ab} |
| Edarbi® | azilsartan |
| Edarbyclor® | azilsartan/chlorthalidone |
| Eprostane | eprosartan |
| Exforge® | valsartan/amlodipine ^a |
| Exforge HCT® | valsartan/amlodipine/HCTZ ^{ab} |
| Hyzaar® | losartan/HCTZ ^{ab} |
| Micardis® | telmisartan ^a |
| Micardis HCT® | telmisartan/HCTZ ^{ab} |
| Teveten® | eprosartan |
| Teveten HCT® | eprosartan/HCTZ ^b |
| Tribenzor® | olmesartan/amlodipine/HCTZ ^a |
| Twynsta® | telmisartan/amlodipine ^a |
| Renin Inhibitors, Combinations | |
| Brand | Generic |
| Amturnide® | aliskiren/amlodipine/HCTZ ^b |
| Tekamlo® | aliskiren/amlodipine |
| Tekturna® | aliskiren |
| Tekturna HCT® | aliskiren/HCTZ ^b |

a - generic available that is a prerequisite agent for step therapy program

b - HCTZ = hydrochlorothiazide

FDA Approved Indications and Dosage

ARBs and ARB Combinations^{1-22,24,25,32,35}

| Agents | HTN | CV Risk ↓ | HTN/ LVH | Post-MI | HF | DMN | Dosing and Administration (adults) |
|---|-----|-----------|----------|---------|------------------|--------|---|
| Atacand (candesartan)* | ✓ | | | | ✓ b d e | | HTN: Initially, 16 mg once daily, lower dose if on diuretic. May be given once or twice daily with total daily doses from 8-32 mg. Larger doses do not appear to have greater effects; limited experience with such doses. HF: Initial, 4 mg once daily. Target dose, 32 mg once daily. |
| Atacand HCT (candesartan/HCTZ)* | ✓ | | | | | | HTN**: Candesartan/HCTZ doses ranging from 8-32 mg of candesartan with 12.5-25 mg of HCTZ were used in trials; Maximum dosage is two candesartan/HCTZ 16/12.5 mg tablets per day (32 mg/day candesartan and 25 mg/day HCTZ) given once daily. |
| Avalide (irbesartan/HCTZ)* | ✓ | | | | | | HTN: Initiate 150/12.5 mg once daily; titrate to 300/12.5 mg, then to a maximum of 300/25 mg once daily if needed. |
| Avapro (irbesartan)* | ✓ | | | | | ✓ c | HTN: Initially, 150 mg once daily; 75 mg in volume- or salt-depleted patients. Patients requiring further BP reduction may be titrated to 300 mg once daily. Patients not adequately treated by the maximum dose of 300 mg once daily are unlikely to derive benefit from a higher dose or twice daily dosing. DMN: Initially 75 mg/day. Target dose is 300 mg/day. There are no data on clinical effects of lower doses in DMN. |
| Azor (olmesartan/ amlodipine)* | ✓ | | | | | | HTN: Initiate amlodipine/olmesartan 5/20 mg once daily (1 to 2 weeks), titrate to maximum of 10/40 mg once daily. |
| Benicar (olmesartan)* | ✓ | | | | | | HTN: Initially, 20 mg once daily; if volume-depleted, begin therapy with 5-10 mg once daily. Range 20-40 mg/day, given once daily. Doses >40 mg/day do not appear to have greater benefit; twice daily dosing has no advantage over the same dose given once daily. |
| Benicar HCT (olmesartan/HCTZ)* | ✓ | | | | | | HTN**: Initial dose one tablet daily. Adjust based on clinical response. Olmesartan and HCTZ have been used together in clinical trials in doses from 10 to 40 mg of olmesartan with 12.5 to 25 mg of HCTZ. Maximum dosage is one tablet of olmesartan/HCTZ 40 mg/25 mg per day. |
| Byvalson (nebivolol/valsartan) | ✓ | | | | | | HTN: 5 mg / 80 mg once daily |
| Cozaar (losartan)* | ✓ | | ✓ a | | | ✓ c | HTN: Initial dose 50 mg once daily; 25 mg if volume depletion or hepatic impairment. May dose once or twice daily; total daily dose range is 25-100 mg. HTN/LVH: Usual initial dose is 50 mg once daily, may be increased to 100 mg once daily, followed by an increase in HCTZ to 25 mg once daily, based on BP response. DMN: Usual initial dose is 50 mg once daily. Dose should be increased to 100 mg once daily based on BP response. |
| Diovan (valsartan)* | ✓ | | | ✓ | ✓ b d | | HTN: Initially, 80 or 160 mg once daily in patients not volume depleted. Patients requiring greater reduction can start at the higher dose. Range 80-320 mg once daily. Post-MI: Initiate 20 mg twice daily as early as 12 hours after MI, titrate over 7 days up to 40 mg twice daily. Titrate to maintenance dose of 160 mg twice daily, as tolerated. HF: Initially, 40 mg twice daily. Titrate to highest dose tolerated, range of 80-160 mg twice daily (maximum dose). |
| Diovan HCT (valsartan/HCTZ)* | ✓ | | | | | | HTN: Initiate with valsartan/HCTZ 160/12.5 mg once daily. Titrate to maximum of 320/25 mg once daily. |

| Agents | HTN | CV Risk ↓ | HTN/ LVH | Post-MI | HF | DMN | Dosing and Administration (adults) |
|---|-----|-----------|----------|---------|----|-----|--|
| Edarbi (azilsartan) | ✓ | | | | | | HTN: The recommended dose is 80 mg once daily. Consider starting dose of 40 mg in patients on high dose diuretics. |
| Edarbyclor (azilsartan/ chorthalidone) | ✓ | | | | | | HTN: The recommended dose is 40/12.5 mg once daily. Maximum dose is 40/25 mg once daily. |
| Exforge (valsartan/ amlodipine)* | ✓ | | | | | | HTN: When used as initial therapy, start with amlodipine/ valsartan 5/160 mg once daily; then titrate upwards as necessary to maximum of 10/320 mg once daily. |
| Exforge HCT (valsartan/ amlodipine/ HCTZ)* | ✓ | | | | | | HTN**: Individualize the dosage by titration of amlodipine, HCTZ, and valsartan. The dosage of one or all components may be increased after 2 weeks. Maximum daily dose is 10 mg amlodipine, 25 mg HCTZ, and 320 mg valsartan. |
| Hyzaar (losartan/HCTZ)* | ✓ | | ✓ a | | | | HTN**: Initial dose losartan/HCTZ 50/12.5 mg once daily. May increase to 2 tablets of 50/12.5 once daily or 1 tablet of 100/25 once daily. Max daily dose is losartan/HCTZ 100/25. HTN/LVH: Initially, 50 mg losartan once daily. May add HCTZ 12.5 mg once daily, may increase losartan to 100 mg, or use losartan/HCTZ 100/12.5 once daily. Maximum daily dosage is losartan/HCTZ 100/25. |
| Micardis (telmisartan)* | ✓ | ✓ | | | | | HTN: Usual initial dose is 40 mg once daily; 20 mg once daily if volume-depleted; range 20-80 mg once daily. CV risk ↓: Recommended dose 80 mg once daily; unknown if doses <80 mg are effective in reduction of cardiac morbidity and mortality. |
| Micardis HCT (telmisartan/HCTZ)* | ✓ | | | | | | HTN**: Telmisartan/ HCTZ studied in clinical trials in doses 20-160 mg of telmisartan with HCTZ 6.25-25 mg. Maximum dose is two telmisartan/ HCTZ 80/12.5 mg tablets per day (160 mg/day telmisartan and 25 mg/day HCTZ). |
| Teveten, eprosartan | ✓ | | | | | | HTN: Initially, 600 mg once daily in patients not volume depleted. Give once or twice daily, total daily doses range 400-800 mg. Limited experience with doses >800 mg/day. |
| Teveten HCT (eprosartan/HCTZ) | ✓ | | | | | | HTN**: Initial dose is one tablet of eprosartan/ HCTZ 600/12.5 mg once daily, which may be increased to one tablet of eprosartan/HCTZ 600/25 mg once daily. If needed, an additional 200-300 mg eprosartan may be given. Eprosartan and HCTZ have been studied together in clinical trials in doses of 600-800 mg/day eprosartan (as single or divided doses) combined with 12.5-25 mg/day HCTZ. Maximum dosage - 900 mg/day eprosartan and 25 mg/day HCTZ. |
| Tribenzor (olmesartan/ amlodipine/HCTZ)* | ✓ | | | | | | HTN: Dose once daily. Dosage may be increased after 2 weeks. The maximum recommended dose is 40/10/25 mg. |
| Twynsta (telmisartan/ amlodipine)* | ✓ | | | | | | HTN: Initial: 1 tablet amlodipine/telmisartan 5/40 mg once daily. Initiate with amlodipine/ telmisartan 5/80 mg once daily in patients requiring larger BP reductions. Maximum dose: 10 mg/day amlodipine/80 mg/day telmisartan. |

HTN=hypertension; LVH=left ventricular hypertrophy; MI=myocardial infarction; DMN=diabetic nephropathy; HCTZ=hydrochlorothiazide, HF=heart failure; CV risk ↓=cardiovascular risk reduction (MI, stroke, death) in high risk patients unable to take ACE inhibitors

All ACEI and ARB single entity agents may be used as monotherapy or in combination for the treatment of hypertension.

*agents available as generics

**To minimize dose independent side effects, it is usual to begin combination therapy only after patients fail to achieve desired effects with monotherapy; combination products may be substituted for previously titrated components.

a - Reduction in the risk of stroke in patients with hypertension and LVH

b - Treatment of heart failure [New York Heart Association (NYHA) class II-IV] in patients unable to tolerate an ACEI

c - Treatment of DMN with an elevated serum creatinine and in patients with type 2 diabetes and HTN

d - In patients intolerant of ACEIs

e - In combination with ACEI

Renin Inhibitors, Renin Inhibitor Combinations^{18,19,24,25}

| Agents | HTN | CV Risk ↓ | HTN/LVH | Post-MI | HF | DMN | Dosing and Administration (adults) |
|---|-----|-----------|---------|---------|----|-----|--|
| Amturnide (aliskiren/ amlodipine/HCTZ) | ✓ | | | | | | HTN: Initial dosing will depend on prior therapy. Dose once-daily. Titrate as needed up to maximum dose- of 300 mg/10 mg/25 mg once daily. |
| Tekamlo (aliskiren/ amlodipine) | ✓ | | | | | | HTN: Initially, aliskiren 150mg/amlodipine 5 mg once daily. Titrate as needed up to maximum dose of 300 mg/10 mg daily. |
| Tekturna (aliskiren) | ✓ | | | | | | HTN: Initially, aliskiren 150 mg once daily. If BP remains uncontrolled, titrate up to 300 mg daily. Maximum dose - 300 mg/day. |
| Tekturna HCT (aliskiren/HCTZ) | ✓ | | | | | | HTN: Usual recommended starting dose is aliskiren/HCTZ 150/12.5 mg once daily. If BP remains uncontrolled after 2-4 weeks of therapy, may be titrated to a maximum of 300 mg aliskiren, 25 mg HCTZ. |

HTN=hypertension; LVH=left ventricular hypertrophy; MI=myocardial infarction; DMN=diabetic nephropathy;
HCTZ=hydrochlorothiazide, HF=heart failure

POLICY**Prior Authorization Criteria for Approval**

Brand ARBs, ARB Combinations, Renin Inhibitors, or Renin Inhibitor combinations will be approved when ONE of the following is met:

1. The patient's medication history includes use of a generic ACEI, generic ACEI combination, generic ARB, or generic ARB combination product in the past 90 days
OR
2. There is documentation that the patient is currently using the requested brand ARB, ARB combination, renin inhibitor, or renin inhibitor combination, OR the requested brand ARB or renin inhibitor in another product (single ingredient or combination)
OR
3. The prescriber states the patient is using the requested brand ARB, ARB combination, renin inhibitor, or renin inhibitor combination or the requested brand ARB or renin inhibitor in another product (single ingredient or combination) **AND** is at risk if therapy is changed
OR
4. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to a generic ACEI, generic ACEI combination or generic ARB combination product.

Length of Approval: 12 months

RATIONALE

ACEIs & ARBs

ACEIs and ARBs are recommended as a first-line pharmacotherapy options for patients with hypertension (HTN), HTN complicated by comorbidities, such as cerebrovascular disease, chronic kidney disease (of diabetic or nondiabetic origin), diabetes, HF, left ventricular dysfunction and MI by national and international clinical guidelines and none of the guidelines have established a preference for one ACEI over another.²³

HTN with Coronary Artery Disease (CAD)³¹

- HF: Patients should be treated with ACE inhibitors (or ARBs), beta-blockers, and aldosterone receptor antagonists. Studies have shown equivalence of benefit of ACE inhibitors and the ARBs candesartan or valsartan in HF with reduced ejection fraction. Either class of agents is effective in lowering BP.
- Chronic stable angina: treatment regimen should include an ACE inhibitor or ARB if there is prior MI, LV systolic dysfunction, diabetes mellitus, or CKD.
- ACS: An ACE inhibitor or an ARB should be added if the patients has anterior MI, if HTN persists, if the patients has evidence of LV dysfunction or HF, or if the patient has diabetes mellitus.

2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults- Report from the Panel Members of the Eighth Joint National Committee (JNC8):²³

- For the general nonblack population ≥ 60 years old (goal BP < 150/90) initial drug treatment options include thiazide-type diuretics, ACEIs, ARBs, or CCB.
- For diabetic patients (goal of BP <140/90) initial drug therapy includes thiazide type diuretics, ACEIs, ARBs, or CCBs.
- For patients with chronic kidney disease (CKD) [goal of BP <140/90], initial therapy options are ACEIs and ARBs.
- Because the majority of CKD patients with HTN will require > 1 drug to achieve goal BP, it is anticipated that an ACEI or ARB will be used as either initial therapy or as second-line therapy in addition to a diuretic or CCB in black patients with CKD.²⁴

2013 ACCF/AHA Guideline for the Management of ST-Elevation Myocardial Infarction (MI) recommends the following:²⁷

An ACEI should be administered within the first 24 hours to all patients with STEMI with anterior location, HF, or EF ≤ 0.40 , unless contraindicated (an alternative is an ARB).

The 2014 AHA/ACC/HRS Guideline for the Management of Patients With Atrial Fibrillation (AF) state:³⁴

- ACEI or ARB treatment is reasonable for primary prevention of new-onset AF in patients with HFrEF.
- ACEI or ARB treatment may be considered for primary prevention of new-onset AF in the setting of hypertension

2016 ACC/AHA/HFSA Focused Update on New Pharmacological Therapy for Heart Failure states:³³

- Inhibition of the renin-angiotensin system with ACEIs or ARBs or ARNI in conjunction with evidence-based beta blockers and aldosterone antagonists in selected patients is

recommended for patients with chronic heart failure with reduced ejection fraction (HFrEF) to reduce morbidity and mortality.

- The use of ARBs to reduce morbidity and mortality is recommended in patients with prior or current symptoms of chronic HFrEF who are intolerant to ACEIs because of cough or angioedema

Diabetes and Kidney Disease

ACEIs

While both ACEIs and ARBs given alone have been found to decrease the progression of microalbuminuria to overt proteinuria, ACEIs currently have the strongest evidence for delaying progression of chronic non-diabetic renal disease as well as nephropathy in type 1 diabetes.³¹

The Standards of Medical Care in Diabetes 2017 from the American Diabetes Association (ADA) states:

- Treatment for hypertension should include drug classes demonstrated to reduce cardiovascular events in patients with diabetes (ACEIs, ARBs, thiazide-like diuretics, or dihydropyridine CCBs). Multiple-drug therapy is generally required to achieve blood pressure targets (but not a combination of ACEIs/ARBs).
- An ACEI/ARB, at the maximum tolerated dose indicated for blood pressure treatment, is the recommended first-line treatment for hypertension in patients with diabetes and urinary albumin-to-creatinine ratio (UACR) ≥ 300 mg/g creatinine or 30–299 mg/g creatinine. If one class is not tolerated, the other should be substituted.
- In patients with type 1 diabetes and HTN and any degree of albuminuria, ACEIs have been shown to reduce loss of GFR and delay the progression of nephropathy.
- In patients with type 2 diabetes, HTN, and UACR 30–299 mg/g creatinine, ACEIs/ARBs have been shown to delay the progression to UACR ≥ 300 mg/g creatinine.
- For patients treated with an ACEI, ARB, or diuretic, serum creatinine/estimated glomerular filtration rate and serum potassium levels should be monitored.

The 2012 update of the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guideline for Diabetes and Chronic Kidney Disease (CKD) state:³⁰

“We suggest using an ACE-I or an ARB in normotensive patients with diabetes and albuminuria levels >30 mg/g who are at high risk of diabetic kidney disease or its progression.”

Safety

ACEIs and ARBs are contraindicated in pregnancy.

Direct Renin Inhibitors

The 2014 Evidence-Based Guideline for the Management of High Blood Pressure in Adults-Report from the Panel Members Appointed to the Eighth Joint National Committee (JNC 8) HTN guidelines note that direct renin inhibitors are not included in the current hypertension guideline recommendations because there were no studies demonstrating their benefits on kidney or CV outcomes.²³ The current ADA and KDOQI guidelines do not provide any recommendations around the use of these medications in the treatment of hypertension in patients with diabetes and/or CKD.^{29,30}

The FDA added a new contraindication against the use of aliskiren with ARBs or ACEIs in patients with diabetes because of the risk of renal impairment, hypotension, and hyperkalemia. A warning was added to avoid use of aliskiren with ARBs or ACEIs in patients with moderate to severe renal impairment (i.e., where glomerular filtration rate [GFR] < 60 mL/min)^{19,26}. The FDA stated that Valtorna (a combination containing aliskiren and valsartan) should not be used in patients with diabetes and Valtorna was removed from the market in July 2012.²⁶

REVISIONS

| | |
|------------|--|
| 05-20-2011 | Revision |
| 07-01-2012 | Revision |
| 01-01-2013 | Revision |
| 09-01-2013 | Revision |
| 04-01-2014 | Policy posted July 15, 2014. |
| | Administrative Update |
| | In Description section: <ul style="list-style-type: none"> ▪ In the Target Drugs chart noted generic availability that is a prerequisite agent for step therapy program on Micardis (telmisartan) and Twynsta (telmisartan / amlodipine) ▪ In ARBs and ARB Combinations chart noted generic availability of Avalide (irbesartan / HCTZ) and Avapro (irbesartan). |
| | References updated |
| 09-17-2014 | Description section <ul style="list-style-type: none"> ▪ Target Drugs and FDA Approved Indications and Dosage charts revised to remove Valtorna (aliskiren/valsartan). |
| | In Policy section: <ul style="list-style-type: none"> ▪ In Item A 3 removed "prescribing physician" and added "provider" to read, "The prescriber states the patient..." |
| | Rationale section updated |
| | In Coding section <ul style="list-style-type: none"> ▪ HCPCS Codes confirmed |
| | References updated |
| 10-01-2015 | Policy published 11-10-2015. Administrative Update retro-effective to 10-01-2015. |
| | Description section updated to include the addition of "eprosartan" to the Target Drugs and updates to the FDA Approved Indications and Dosage chart. |
| | Rationale section updated |
| | Removed Coding section |
| | References updated |
| 10-01-2015 | Policy published 12-22-2015. Updates retro-effective to 10-01-2015. |
| | Description section updated to include updates to the FDA Approved Indications and Dosage chart. |
| | References updated |
| 09-01-2016 | Description section updated |
| | In Policy section <ul style="list-style-type: none"> ▪ In Item 1 added "in the past 90 days" to read "The patient's medication history includes use of a generic ACEI, generic ACEI combination, generic ARB, or generic ARB combination product in the past 90 days" |
| | Rationale section updated |

| | |
|------------|---|
| | Revision section updated to remove details of the 05-20-2011, 07-01-2012, 01-01-2013, and 09-01-2013 updates. |
| | References updated |
| 10-01-2016 | Policy published 10-12-2016. Policy retro-effective to 10-01-2016. |
| | In Description section: <ul style="list-style-type: none"> ▪ Added Byvalson nebivolol/valsartan to the Target Drug and FDA Approved Indications and Dosage chart. |
| | References updated |
| 12-01-2016 | Policy published 12-29-2016. Policy retro-effective to 12-01-2016. |
| | In Description section: <ul style="list-style-type: none"> ▪ Updated Target Drugs chart and FDA Indications and Dosage chart noting generic availability of Azor, Benicar, Benicar/HCTZ, and Tribenzor. |
| 11-01-2017 | Description section updated |
| | Rationale section update |
| | References updated |

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