

Pharmacy Medical Necessity Guidelines: Antihypertensive Medications

Effective: September 10, 2024

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan			Fax Numbers: RXUM: 617.673.0939

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Medications in the guideline are indicated for the treatment of hypertension either alone or in combination with other antihypertensive agents.

In addition to the diagnosis of hypertension, the following medications have additional cardiovascular indications:

- Candesartan - Treatment of heart failure to reduce the risk of death from cardiovascular causes and reduce heart failure hospitalizations
- Irbesartan - Treatment of diabetic nephropathy in patients with type 2 diabetes, hypertension, an elevated serum creatinine, and proteinuria
- Telmisartan - For reduction of the risk of myocardial infarction (MI), stroke, or death from cardiovascular causes in patients 55 years and older at high risk of developing major cardiovascular events who are unable to take angiotensin-converting enzyme (ACE) inhibitors.
- Valsartan - For the treatment of heart failure (New York Heart Association [NYHA] class II to IV) and to reduce cardiovascular mortality in clinically stable patients with left ventricular failure or left ventricular dysfunction following MI.
- Carvedilol extended-release - For the treatment of mild to severe chronic heart failure and left ventricular dysfunction following myocardial infarction in clinically stable patients
- Cardizem LA and Matzim LA – Improve exercise tolerance in patients with chronic stable angina
- Eplerenone - To improve survival of stable patients with symptomatic heart failure with reduced ejection fraction ($\leq 40\%$) (HFrEF) after an acute MI.

Nimodipine is only indicated for the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their post-ictus neurological condition (ie, Hunt and Hess grades I to V). It is not indicated for hypertension.

Generic Name	Reference Brand Name*	Utilization Management
Angiotensin II Receptor Blockers (ARBs)		
Covered		
Irbesartan tablet*	Avapro	Covered
Losartan tablet*	Cozaar	Covered
Olmesartan medoximil tablet*	Benicar	Covered
Telmisartan*	Micardis	Covered
Valsartan tablet*	Diovan	Covered
Prior Authorization		
Azilsartan medoxomil tablet	Edarbi	PA
Candesartan cilexetil tablet*	Atacand	PA
Beta-blockers		
Step Therapy		
Carvedilol phosphate capsule SR 24HR*	Coreg CR	ST
Nebivolol HCl tablet*	Bystolic	ST

Prior Authorization		
Metoprolol tartrate 37.5 and 75 mg	Metoprolol tartrate	PA
Calcium Channel Blockers		
Diltiazem HCl coated beads tablet 24HR tablets	Cardizem LA, Matzim LA	PA
Isradipine capsule	Dynacirc	PA
Nimodipine	Nymalize	PA
Direct Renin Inhibitors		
Aliskiren fumarate tablet*	Tekturna	PA;QL (1 unit/day)
Selective Aldosterone Receptor Antagonist		
Eplerenone tablet*	Inspira	PA
Combinations Products		
Covered		
Irbesartan/HCTZ tablet*	Avalide	Covered
Olmesartan medoximil/hydrochlorothiazide tablet*	Benicar HCT	Covered
Valsartan/amlodipine tablet*	Exforge	Covered
Valsartan/HCTZ tablet*	Diovan HCT	Covered
Step Therapy		
Olmesartan medoximil/amlodipine tablet*	Azor	ST
Prior Authorization		
Aliskiren/hydrochlorothiazide tablet	Tekturna HCT	PA;QL (1 unit/day)
Amlodipine/atorvastatin tablet*	Caduet	PA
Amlodipine/valsartan/hydrochlorothiazide tablet*	Exforge-HCT	PA
Candesartan/hydrochlorothiazide*	Atacand-HCT	PA
Telmisartan/hydrochlorothiazide*	Micardis-HCT	PA

*Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

ST: Prior authorization required if step therapy criteria are not met at the point-of-sale.

Reference the Tufts Health Public Plans Preferred Drug Lists (PDLs) for a list of preferred products within each therapeutic class that are covered without restriction.

COVERAGE GUIDELINES

The plan may authorize coverage of an antihypertensive medication for Members when **all** of the following criteria are met:

Nebivolol

1. The Member is stable on the requested medication

OR

2. The Member had an inadequate response, intolerance, or contraindication to two alternative beta-blockers (e.g., metoprolol, bisoprolol) or the provider indicates that therapy with alternative beta-blockers is not clinically appropriate for the member

Carvedilol Extended-Release

1. The Member is stable on the requested medication

OR

2. The Member had an inadequate response, intolerance, or contraindication to immediate-release carvedilol and at least one additional generic beta-blocker (e.g., metoprolol succinate, bisoprolol) or the provider indicates treatment with alternative beta blockers is not clinically appropriate for the member

Eplerenone

1. The Member had an inadequate response, intolerance, or contraindication to another aldosterone antagonist (e.g., spironolactone) or the provider indicates clinical inappropriateness of therapy with another aldosterone antagonist

Metoprolol 37.5 and 75 mg

1. Documentation that treatment with generic metoprolol tartrate 25, 50, and 100 mg tablets is not clinically appropriate for the member

Aliskiren

1. The Member has been stable on the requested medication

OR

2. The Member had an inadequate response, intolerance, or contraindication to at least three alternative generic antihypertensive medications, one of which must be an angiotensin converting enzyme inhibitor (ACE-I) (e.g., lisinopril, captopril, benazepril, fosinopril) and one of which must be an angiotensin receptor II blocker (ARB) (e.g., irbesartan, losartan, valsartan) or the provider indicates that treatment with other antihypertensive medications is not clinically appropriate for the member

Angiotensin II Receptor Blockers (ARBs)

1. The Member had an inadequate response, intolerance, or contraindication to therapy with one of the following: irbesartan, irbesartan/HCTZ, losartan, losartan/HCTZ, olmesartan, olmesartan/HCTZ, telmisartan, valsartan, valsartan/HCTZ, valsartan/amlodipine or the provider indicates that treatment with other antihypertensive medications is not clinically appropriate for the member

AND

2. **Edarbi only:** The Member had an inadequate response, intolerance, or contraindication to a course of therapy with one generic angiotensin converting enzyme inhibitor (ACE-I) (e.g., lisinopril, captopril, benazepril, fosinopril) or the provider indicates that treatment with ACE-Is is not clinically appropriate for the member

Calcium Channel Blocker

1. The Member is diagnosed with or is at risk for having subarachnoid hemorrhage or stroke*

OR

2. The Member had an inadequate response, intolerance, or contraindication to a course of therapy with two of the preferred calcium channel blockers (e.g., amlodipine, diltiazem, felodipine, nifedipine, verapamil) or the provider indicates that treatment with preferred calcium channel blockers is not clinically appropriate for the member

Combination medication

1. The Member is stable on the requested medication or on the individual ingredients

AND

2. The provider indicates concern with the use of the individual medications

*Diagnoses indicating at risk for stroke may include, but is not limited to, hypertensive crisis, cerebral vasculitis, acute onset headache syndromes, cerebral vasoconstriction

LIMITATIONS

1. The coverage of amlodipine/atorvastatin, Amturnide, Tekamlo, Tekturna, and Tekturna HCT is limited to one tablet per day.
2. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Arnett DK, Blumenthal RS, Albert MA, et al. 2019 ACC/AHA guideline on the primary prevention of cardiovascular disease. *JACC*. 2019;74:e177-232.
2. Atacand (candesartan) [prescribing information]. Baudette, MN: ANI Pharmaceuticals, Inc; June 2020.
3. Atacand HCT (candesartan-hydrochlorothiazide) [prescribing information]. Baudette, MN: ANI Pharmaceuticals, Inc; May 2020.
4. Avapro (irbesartan) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; September 2021.

5. Benicar (olmesartan) [prescribing information]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc.; July 2023.
6. Benicar HCT (4 lmesartan-hydrochlorothiazide) [prescribing information]. South Plainfield, NJ: Cosette Pharmaceuticals, Inc.; July 2023 .
7. Bystolic (nebivolol) [prescribing information]. Madison, NJ: Allergan USA, Inc.; June 2023.
8. Caduet (amlodipine/atorvastatin) [prescribing information]. New York, NY: Pfizer, Inc; June 2024 .
9. Cardizem LA (diltiazem HCl extended-release) [prescribing information]. Bridgewater, NJ: Bausch Health US, LLC; May 2019.
10. Carey RM, Calhoun DA, Barks GL, et al. Resistant hypertension: detection, evaluation, and management: a scientific statement from the American Heart Association. *Hypertension*. 2018;72:e53-e90.
11. Coreg CR (carvedilol extended release) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; November 2020.
12. Diovan (valsartan) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2024 .
13. Diovan HCT (valsartan-hydrochlorothiazide). East Hanover, NJ: Novartis Pharmaceuticals Corp; July 2024 .
14. Edarbi (azilsartan medoxomil) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; April 2023.
15. Hillis LD, Smith PK, Anderson JL, et al. 2011 ACCF/AHA Guideline for Coronary Artery Bypass Graft Surgery: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2011;124(23):2610-42.
16. Inspra (eplerenone) [prescribing information]. New York, NY: Pfizer; October 2021.
17. Isradipine [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc; November 2023 .
18. James PA, Oparil S, Carter BL, et al. 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). *JAMA*. 2014;311(5):507-20.
19. Matzim LA (diltiazem HCl extended-release) [prescribing information]. Parsippany, NJ: Actavis Pharma, Inc.; January 2021.
20. Micardis (telmisartan) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; December 2022.
21. Micardis HCT (telmisartan-hydrochlorothiazide) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; December 2022.
22. Nymalize (nimodipine) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals, LLC; May 2022.
23. Tekturna (aliskiren) [prescribing information]. Basking Ridge, NJ: Noden Pharma USA, Inc; May 2023.
24. Tekturna HCT (aliskiren-hydrochlorothiazide) [prescribing information]. Orlando, FL: Noden Pharma USA, Inc; November 2022 .
25. Yancy CW, Jessup M, Bozkurt B, et al; American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. *Circulation*. 2013;128(16):e240-e327.
26. Whelton PK, Carey RM, Aronow WS, et al. 2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the prevention, detection, evaluation, and management of high blood pressure in adults: executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Hypertension* 2018;71:1269-1324.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective December 1, 2023, updated previous trial language for all products.
2. September 10, 2024: Administrative change to fax number.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined

population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

[Provider Services](#)