Pharmacy Medical Necessity Guidelines: Antihypertensive Medications

Effective: September 21, 2020

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:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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.
- Coreg CR - 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 - For the management of chronic stable angina
- Inspra - To improve survival of stable patients with symptomatic heart failure with reduced ejection fraction (≤40%) (HFrEF) after an acute myocardial infarction.

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 postictus 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
Eprosartan mesylate tablet*	Teveten	PA
Beta-blockers		
Step Therapy		
Carvedilol phosphate capsule SR 24HR	Coreg CR	ST
Nebivolol HCl tablet	Bystolic	ST;QL (1 unit/day)
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*	Inspra	PA;QL (2 units/day)
Combinations Products		
Covered		
Irbesartan/HCTZ tablet*	Avalide	Covered
Olmesartan medoxomil/ hydrochlorothiazide tablet*	Benicar HCT	Covered
Valsartan/amlodipine tablet*	Exforge	Covered; QL (1 unit/day)
Valsartan/HCTZ tablet*	Diovan HCT	Covered
Step Therapy		
Olmesartan medoxomil/amlodipine tablet*	Azor	ST
Prior Authorization		
Aliskiren/amlodipine tablet	Tekamlo	PA;QL (1 unit/day)
Aliskiren/amlodipine/hydrochlorothiazide tablet	Amturnide	PA;QL (1 unit/day)
Aliskiren/hydrochlorothiazide tablet	Tekturna HCT	PA;QL (1 unit/day)
Amlodipine/valsartan/hydrochlorothiazide tablet*	Exforge-HCT	PA;QL (1 unit/day)
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:

Bystolic

1. The Member is stable on the requested medication

OR

2. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with two alternative beta-blockers (e.g., metoprolol, bisoprolol)

Coreg CR

1. The Member is stable on the requested medication

OR

2. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with immediate-release carvedilol and at least one additional generic beta blocker (e.g., metoprolol succinate, bisoprolol)

Eplerenone

1. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with another aldosterone antagonist (e.g., spironolactone)

Metoprolol 37.5 and 75 mg

1. Provider documentation of clinical inappropriateness of therapy with generic metoprolol tartrate 25, 50, and 100 mg tablets

Tekturna

1. The Member has been stable on the medication for a duration of at least 3 months

OR

2. The Member failed a course of therapy , or the provider indicates clinical inappropriateness of therapy with 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)

Angiotensin II Receptor Blockers (ARBs)

1. The Member failed a course of therapy or the provider indicates clinical inappropriateness of therapy with one of the following: irbesartan, irbesartan/HCTZ, losartan, losartan/HCTZ, olmesartan, olmesartan/HCTZ, telmisartan, valsartan, valsartan/HCTZ, valsartan/amlodipine

AND

2. **Edarbi only:** The Member tried a course of therapy or the provider indicates clinical inappropriateness of therapy with one generic angiotensin converting enzyme inhibitor (ACE-I) (e.g., lisinopril, captopril, benazepril, fosinopril)

Calcium Channel Blocker

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

OR

2. The Member failed a course of therapy with two of the preferred calcium channel blockers (e.g., amlodipine, diltiazem, felodipine, nifedipine, verapamil)

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 Amturnide, Azor, Bystolic, Exforge, Exforge HCT, Tekamlo, Tekturna, and Tekturna HCT is limited to one tablet per day.
2. The coverage of eplerenone is limited to two tablets per day.
3. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

CODES

None

REFERENCES

1. Atacand (candesartan) [prescribing information]. Wilmington, DE: AstraZeneca LP; February 2016.
2. Atacand HCT (candesartan-hydrochlorothiazide) [prescribing information]. Wilminton, DE: AstraZeneca LP; February 2016.
3. Avapro (irbesartan) [prescribing information]. Bridgewater, NJ: Sanofi-Aventis; July 2018.
4. Benicar (olmesartan) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo; October 2019.
5. Bystolic (nebivolol) [prescribing information]. Irvine, CA: Allergan Pharmaceuticals; November 2017.
6. Cardizem LA (diltiazem) [prescribing information]. North Chicago, IL: Abbott Laboratories; November 2016.
7. Coreg CR (carvedilol extended release) [prescribing information]. Research Triangle Park, NC: GlaxoSmithKline; September 2017.
8. Diovan (valsartan) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; January 2017.
9. Diovan HCT (valsartan-hydrochlorothiazide). East Hanover, NJ: Novartis Pharmaceuticals Corp; June 2019.
10. Dynacirc CR (isradipine) [prescribing information]. Research Triangle Park, NC; GlaxoSmithKline; February 2009.
11. Edarbi (azilsartan medoxomil) [prescribing information]. Atlanta, GA: Arbor Pharmaceuticals; March 2020.
12. 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.
13. 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.
14. Teveten (eprosartan) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2014.
15. Micardis (telmisartan) [prescribing information]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals Inc; February 2018.
16. Matzim LA (diltiazem) [prescribing information]. Parsippany, NJ: Actavis Pharma; December 2014.
17. Inspra (eplerenone) [prescribing information]. New York, NY: Pfizer; May 2018.
18. Nymalize (nimodipine) [prescribing information]. Atlanta, GA: Arbor; September 2013.
19. Tekturna (aliskiren) [prescribing information]. Boston, MA: Noden Pharma USA, Inc; November 2017.
20. Tekturna HCT (aliskiren-hydrochlorothiazide) [prescribing information]. Boston, MA: Noden Pharmacy USA, Inc; November 2016.
21. 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.
22. 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

April 14, 2015: Consolidated individual antihypertensive medication criteria; modified approval duration

Subsequent endorsement date(s) and changes made:

1. September 16, 2015: Approval duration approved for life of plan
2. January 1, 2016: Administrative change to rebranded template
3. April 12, 2016: Added brand metoprolol 37.5 and 75 mg tablets. Removed Limitation #3 "Requests for quantities that exceed the quantity limit will be reviewed according to the Quantity Limit criteria."
4. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria for Coreg CR and angiotensin II receptor blockers (ARBs) to require a trial and failure with at least two generic agents from the same therapeutic class.
5. July 11, 2017: Removed penbutolol from Medical Necessity Guideline due to product discontinuation. Reflected generic availability of Inspra. Clarified for eplerenone approval criteria to require clinical inappropriateness of therapy with another aldosterone antagonist. Provided examples of therapeutic trial options for Bystolic and Coreg CR.
6. November 13, 2018: Administrative changes made to template.

7. March 12, 2019: Effective 4/1/2019, updated MNG to indicate that the following agents will be covered without prior authorization: irbesartan, irbesartan/HCTZ, valsartan, valsartan/HCTZ, valsartan/amlodipine. Effective 4/1/2019, the following agents will be moved from PA to Step Therapy: telmisartan, olmesartan/amlodipine. Effective 4/1/2019, the following agent will be moved from Not Covered to PA: candesartan/HCTZ. Criteria for angiotensin receptor blockers and Tekturna were updated to reflect updates in preferred products in the ARB class. Criteria for generic ARBs updated to require trial and failure with only one preferred ARB.
8. April 14, 2020: No changes.
9. September 15, 2020: Updated MNG to indicate that coverage for Olmesartan, Olmesartan/HCTZ, and telmisartan has been updated from Step Therapy to Covered. Updated ARB criteria to include olmesartan, olmesartan/HCTZ, and telmisartan as previous trial options.

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.