Clinical Policy: ACEI and ARB Duplicate Therapy

Reference Number: CP.PMN.61
Effective Date: 08.01.14
Last Review Date: 05.20
Line of Business: Medicaid

Revision Log

See Important Reminder **at the end of this policy for important regulatory and legal information.**

Description

Angiotensin-converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) act on the renin-angiotensin system. Concurrent use of an ACEI and an ARB is considered duplicate therapy.

FDA Approved Indication(s)

Most ACEIs and ARBs are indicated for the treatment of hypertension and heart failure. Some are also indicated for diabetic nephropathy, myocardial infarction prophylaxis, proteinuria, reduction of cardiovascular mortality, and stroke prophylaxis.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that ACEI and ARB duplicate therapy is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. ACEI and ARB Duplicate Therapy (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Member is currently receiving ACEI and ARB combination therapy for chronic heart failure, has received the combination for at least 30 days, and is responding positively to therapy;
   b. Member is being titrated to, or tapered from, another ACEI or ARB;
2. Provider documents that he/she is aware of duplicative therapy;
3. Dose does not exceed the FDA-approved maximum recommended dose for the relevant ACEI and ARB.

Approval duration:
Chronic heart failure – 12 months
Cross-taper – 3 months

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. ACEI and ARB Duplicate Therapy (must meet all)**:**

1. Currently receiving ACEI and ARB combination therapy via Centene benefit or member has previously met initial approval criteria;

2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed the FDA-approved maximum recommended dose for the relevant ACEI and ARB.

Approval duration:
Chronic heart failure – 12 months
Cross-taper – 3 months (limited to 6 months total)

B. Other diagnoses/indications: Not applicable

III. Diagnoses/Indications for which coverage is NOT authorized: Not applicable

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ACEI: angiotensin-converting enzyme inhibitor
ARB: angiotensin receptor blocker
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

V. Dosage and Administration

Drug Name	Maximum Dose
ACEIs	
Benazepril (Lotensin®)	80 mg/day
Captopril (Capoten®)	450 mg/day
Enalapril (Vasotec®, Epaned®)	40 mg/day
Fosinopril (Monopril®)	80 mg/day
Lisinopril (Prinivil®, Zestril®, Qbrelis®)	80 mg/day
Moexipril (Univasc®)	30 mg/day
Perindopril (Aceon®)	16 mg/day
Quinapril (Accupril®)	80 mg/day
Ramipril (Altace®)	20 mg/day
Trandolapril (Mavik®)	8 mg/day
ARBs	
Azilsartan (Edarbi®)	80 mg/day
Candesartan (Atacand®)	32 mg/day
Eprosartan (Teveten®)	900 mg/day
Irbesartan (Avapro®)	300 mg/day
Losartan (Cozaar®)	100 mg/day
Olmesartan (Benicar®)	40 mg/day
Telmisartan (Micardis®)	80 mg/day
Valsartan (Diovan®)	320 mg/day
Neprilysin Inhibitor/ARB	
Entresto® (sacubitril/valsartan)	194/206 mg/day

VI. Product Availability

Drug Name	Availability
ACEIs	
Benazepril (Lotensin)	Tablet: 5 mg, 10 mg, 20 mg, 40 mg
Captopril (Capoten)	Tablet: 12.5 mg, 25 mg, 50 mg, 100 mg
Enalapril (Vasotec, Epaned)	Tablet: 2.5 mg, 5 mg, 10 mg, 20 mg Oral solution: 1 mg/mL
Fosinopril (Monopril)	Tablet: 10 mg, 20 mg, 40 mg
Lisinopril (Prinivil, Zestril, Qbrelis)	Tablet: 2.5 mg, 5 mg, 10 mg, 20 mg, 30 mg, 40 mg Oral solution: 1 mg/mL
Moexipril (Univasc)	Tablet: 7.5 mg, 15 mg
Perindopril (Aceon)	Tablet: 2 mg, 4 mg, 8 mg
Quinapril (Accupril)	Tablet: 5 mg, 10 mg, 20 mg, 40 mg
Ramipril (Altace)	Capsule: 1.25 mg, 2.5 mg, 5 mg, 10 mg
Trandolapril (Mavik)	Tablet: 1 mg, 2 mg, 4 mg
ARBs	
Azilsartan (Edarbi)	Tablet: 40 mg, 80 mg
Candesartan (Atacand)	Tablet: 4 mg, 8 mg, 16 mg, 32 mg
Eprosartan (Teveten)	Tablet: 600 mg
Irbesartan (Avapro)	Tablet: 75 mg, 150 mg, 300 mg
Losartan (Cozaar)	Tablet: 25 mg, 50 mg, 100 mg
Olmesartan (Benicar)	Tablet: 5 mg, 20 mg, 40 mg
Telmisartan (Micardis)	Tablet: 20 mg, 40 mg, 80 mg
Valsartan (Diovan)	Tablet: 40 mg, 80 mg, 160 mg, 320 mg
Neprilysin Inhibitor/ARB	
Entresto (sacubitril/valsartan)	Tablet: 24/26 mg, 49/51 mg, 97/103 mg

VII. References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2020. Available at: http://www.clinicalpharmacology-ip.com/. Accessed February 25, 2020.
2. Makani H, Bangalore S, Desouza KA, Shah A, Messerli FH. Efficacy and safety of dual blockade of the renin-angiotensin system: meta-analysis of randomised trials. BMJ 2013;346:f360.
3. Fried LF, Emanuele N, Zhang JH, et al. Combined angiotensin inhibitor treatment of diabetic nephropathy. N Engl J Med 2013; 369(20).
4. Mann JF, Schmieder RE, McQueen M, et al. Renal outcomes with telmisartan, ramipril, or both, in people at high vascular risk (the ONTARGET study); a multicentre, randomized, double-blind, controlled trial. Lancet. 2008;372(9638):547-53.
5. 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):507-520. doi:10.1001/jama.2013.284427.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Converted to new template; Added FDA dosage limit; Updated references.	03.16	05.16
Converted to new template; Added duration of 30 days to initial requirement related to continuity of care/heart failure for clarity; Specified approval duration of 3 months for cross-taper for initial and re-auth; limited approval duration for cross-taper to total of 6 months; Added documentation of positive response to therapy on re-auth; Updated references.	03.17	05.17
2Q 2018 annual review: no significant changes; references reviewed and updated.	02.22.18	05.18
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.05.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.25.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.