CENTENE Corporation

Clinical Policy: Cardiovascular Agents: Angina, Hypertension & Heart Failure

Reference Number: OH.PHAR.PPA.29
Effective Date: 01-01-2020
Last Review Date: 11.20
Line of Business: Medicaid

Coding Implications
remove if no codes added
Revision Log

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

Description

See **Appendix A** for list of preferred and non-preferred Cardiovascular Agents

FDA Approved Indication(s): Varies by drug product, please see package insert; clinical pharmacology or other appropriate clinical reference.

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 Buckeye Health Plan® that Non-Preferred medication is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prescribed medication requires prior authorization as noted in appendix A (must meet 1,2,3, and 4 OR 5)

1. **Prescribed indication is FDA-approved or supported by standard pharmacopeias**
2. **Member must meet labeled age requirements for the medication**
3. **Member has failed therapeutic trials of no less than 30 days with TWO (2) preferred medications within the same class unless one of the following (a,b, or c)**
   a. Allergy to all medications not requiring prior approval
   b. Contraindication to all medications not requiring prior approval
   c. History of unacceptable/toxic side effects to medications not requiring prior approval
4. **The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated**
5. **If there is a specific indication for a medication requiring prior approval, for which medications not requiring prior approval are not indicated, then may approve the requested medication.** This medication should be reviewed for need at each request for reauthorization.

Approval duration: 12 months

II. Initial Approval Criteria if prescribed medication is Ivabradine (Corlanor)

A. Heart Failure (must meet all):

1. Diagnosis of stable, symptomatic heart failure
2. Age ≥ 6 months;
3. **Baseline LVEF ≤ 35% for adults or ≤ 45% for pediatrics;**
4. Member is in sinus rhythm with a resting heart rate of 70 bpm or higher
5. Heart failure symptoms persisting with maximally tolerated doses of appropriate beta blockers recommended for heart failure, or patient has a contraindication to beta blocker therapy.

Approval duration: 12 months

III. Initial Approval Criteria if prescribed medication is Valsartan/sacubitril (Entresto)

A. Diagnosis of chronic heart failure (NYHA Class II-IV)

1. **Baseline Left ventricular ejection fraction less than or equal to 40%**
2. **Age ≥ 18 years;**
3. **At the time of request, member has none of the following contraindications:**
   a. Concomitant use with ACE inhibitors;
   b. If member has a diagnosis of diabetes, concomitant use with aliskiren;
4. Dose does not exceed sacubitril 194 mg/valsartan 206 mg (2 tablets) per day.

Approval duration: 12 months

<u>****Please see preferred and non-preferred charts below in Appendix A****</u>

Appendix A

CHRONIC STABLE ANGINA

NO PA REQUIRED "PREFERRED"	REQUIRED "PREFERRED"
RANOLAZINE (generic of Ranexa')	

ACE INHIBITORS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BENAZEPRIL (generic of Lotensin®) CAPTOPRIL (generic of Capoten®) ENALAPRIL (generic of Vasotec®) EPANED' (enalapril oral solution) FOSINOPRIL (generic of Monopril®) LISINOPRIL (generic of Zestril®, Prinivil®) MOEXIPRIL (generic of Univasc®) PERINDOPRIL ERBUMINE (generic of Aceon®) QUINAPRIL (generic of Accupril®) RAMIPRIL (generic of Altace®) TRANDOLAPRIL (generic of Mavik®)	QBRELIS™ (lisinopril oral solution)

ACE INHIBITORS/CCB COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE/BENAZEPRIL (generic of Lotrel') VERAPAMIL/TRANDOLAPRIL (generic of Tarka®)	PRESTALIA' (perindopril-amlodipine tablet)

ACE INHIBITORS/DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
BENAZEPRIL/HCTZ (generic of Lotensin HCT®) CAPTOPRIL/HCTZ (generic of Capozide®) ENALAPRIL/HCTZ (generic of Vaseretic®) FOSINOPRIL/HCTZ (generic of Monopril HCT') LISINOPRIL/HCTZ (generic of Zestoretic®, Prinzide®) MOEXIPRIL/HCTZ (generic of Uniretic®) QUINAPRIL/HCTZ (generic of Accuretic®)	

ALDOSTERONE ANTAGONIST

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
SPIRONOLACTONE (generic of Aldactone®)	CAROSPIR' SUSP (spironolactone suspension)

ALPHA-BETA BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
CARVEDILOL (generic of Coreg®) LABETALOL (generic of Trandate®)	CARVEDILOL ER (generic of COREG CR™)

ANGIOTENSIN II RECEPTOR ANTAGONISTS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
IRBESARTAN (generic of Avapro®) LOSARTAN (generic of Cozaar®) VALSARTAN (generic of Diovan®)	CANDESARTAN (generic of Atacand®) EDARBI® (azilsartan) EPROSARTAN (generic of Teveten®) OLMESARTAN (generic of Benicar®) TELMISARTAN (generic of Micardis®)

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED "	PA REQUIRED "NON-PREFERRED"
IRBESARTAN-HCTZ (generic of Avalide®) LOSARTAN-HCTZ (generic of Hyzaar®) VALSARTAN/HCTZ (generic of Diovan HCT®)	CANDESARTAN/HCTZ (generic of Atacand HCT®) EDARBYCLOR™ (azilsartan/ chlorthalidone) OLMESARTAN/HCTZ (generic of Benicar HCT®) TELMISARTAN/HCTZ (generic of Micardis HCT®) TEVETEN HCT® (eprosartan/HCTZ)

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ BETA BLOCKERS COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Trial of Preferred Beta blocker and a preferred angiotesnsin II receptor antagonist	BYVALSONTM (nebivolol/valsartan)

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ CALCIUM CHANNEL BLOCKER COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE/OLMESARTAN (generic of Azor®) AMLODIPINE/ TELMISARTAN (generic of Twynsta®) AMLODIPINE/VALSARTAN (generic of Exforge®)	

ANGIOTENSIN II RECEPTOR ANTAGONISTS/ CALCIUM CHANNEL BLOCKER/DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE/ VALSARTAN /HCTZ (generic of Exforge® HCT)	OLMESARAN/AMLODIPINE/ HCTZ (generic of Tribenzor®)

ANGIOTENSIN II RECEPTOR ANTAGONIST/ NEPRILYSIN INHIBITOR COMBINATION*

CLINICAL PA REQUIRED "PREFERRED"	NO PA REQUIRED "NON-PREFERRED"
ENTRESTOTM (valsartan/sacubitril)	

* Note: Clinical criteria must be met

BETA BLOCKERS

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ACEBUTOLOL (generic of Sectral®) ATENOLOL (generic of Tenormin®) BETAXOLOL (generic of Kerlone®) BISOPROLOL FUMARATE (generic of Zebeta®) METOPROLOL SUCCINATE (generic of Toprol XL®) METOPROLOL TARTRATE (generic of Lopressor®) NADOLOL (generic of Corgard®) PINDOLOL (generic of Visken®) PROPRANOLOL (generic of Inderal®) PROPRANOLOL ER (generic of Inderal LA®) SOTALOL (generic of Betapace®) SOTALOL AF (generic of Betapace AF') TIMOLOL (generic of Blocadren®)	BYSTOLIC® (nebivolol) INNOPRAN XL® (propranolol) KAPSPARGO SPRINKLE™ (metoprolol succinate) LEVATOL® (penbutolol) SOTYLIZE' oral solution (sotalol solution)

BETA-BLOCKERS/DIURETIC COMBINATION

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
ATENOLOL/CHLORTHALIDONE (generic of Tenoretic®) BISOPROLOL/HCTZ (generic of Ziac®) DUTOPROL® (metoprolol succinate/HCTZ) METOPROLOL/HCTZ (generic of Lopressor HCT') NADOLOL/BENDROFLUMETHIAZIDE (generic of Corzide®) PROPRANOLOL/HCTZ (generic of Inderide®)	

CALCIUM CHANNEL BLOCKERS- DIHYDROPYRIDINE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
AMLODIPINE (generic of Norvasc®) FELODIPINE (generic of Plendil®) NICARDIPINE (generic of Cardene®) NIFEDIPINE ER (generic of Procardia XL', Adalat CC®) NIFEDIPINE IMMEDIATE RELEASE (generic of Procardia')	ISRADIPINE (generic of Dynacirc') KATERZIA® oral suspension (amlodipine) NIMODIPINE (generic of Nimotop®)* NYMALIZE oral solution (nimodipine solution)* NISOLDIPINE (generic of Sular')

* Note: **nimodipine only approvable for 21 days after subarachnoid hemorrhage.**

CALCIUM CHANNEL BLOCKERS- NON-DIHYDROPYRIDINE

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
DILTIAZEM (generic of Cardizem') DILTIAZEM ER (generic of Cardizem CD' q24h, Tiazac') DILTIAZEM SR (generic of Cardizem SR' q12h) VERAPAMIL (Generic of Calan') VERAPAMIL SR/ER (Generic of Calan SR', Isoptin SR', Verelan')	DILTIAZEM 24H ER tablet (generic of Cardizem LA®) VERAPAMIL ER PM (generic of Verelan PM')

DIRECT RENIN INHIBITORS* and combinations

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
Trial of any one preferred anti-hypertensive agent	ALISKIREN (generic Tekturna®) TEKTURNA HCT® (aliskiren/HCTZ)

HYPERPOLARIZATION-ACTIVATED CYCLE NUCLEOTIDE-GATED CHANNEL INBITOR*

NO PA REQUIRED "PREFERRED"	PA REQUIRED "NON-PREFERRED"
	CORLANOR® (ivabradine)

- Note: Clinical criteria must be met

V. Diagnoses/Indications for which coverage is NOT authorized:

Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

VI. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PA: Prior Authorization
ER: Extended Release

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

*****See above tables for preferred alternatives***** *Dosing varies by drug product. See FDA approved dosing and administration.*

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- *See package insert; clinical pharmacology or other appropriate clinical reference.*

VII. Dosage and Administration: varies by drug product. See package insert; clinical pharmacology or other appropriate clinical reference for FDA approved dosing and administration

VIII. Product Availability: See package insert; clinical pharmacology or other appropriate clinical reference for product availability

VII. References. Refer to package insert.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
New policy created.	10.19	
Added Katerzia oral suspension as a non-preferred calcium channel blocker	03.20	
Changed criteria point 3 for ranolazine to: 3. Member has had a therapeutic failure to no less than a 30 day trial of a beta blocker, a diltiazem product, **or** a nitrate (excluding sublingual nitroglycerin), or contraindications to these agents exist; indicating that a patient only needs to try/fail just one of the three preferred agents rather than try/fail all three.	06.20	
Ranolazine (generic Ranexa) changed to preferred, no PA required.	11.20	

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.

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