Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy

CENTENE® Corporation

Clinical Policy: Rexlemestrocel-L (Revascor)

Reference Number: CP.PHAR.728
Effective Date: FDA Approval Date
Last Review Date: 05.26
Line of Business: Commercial, HIM/ICHRA, Medicaid

Coding Implications
Revision Log

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

Description

Rexlemestrocel-L (Revascor®) is an allogeneic mesenchymal precursor cell therapy.

FDA Approved Indication(s) [Pending]

Revascor is indicated for the treatment of patients with:

- *Advanced heart failure (criteria set I.A)*: Advanced, high-risk ischemic heart failure with reduced ejection fraction (HFrEF) with inflammation
- *End-stage heart failure (criteria set I.B)*: End-stage ischemic HFrEF with a left ventricular assist device (LVAD)

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.

All requests reviewed under this policy **require Precision Drug Action Committee (PDAC) Utilization Management Review.** Refer to CC.PHAR.21 for process details.

It is the policy of health plans affiliated with Centene Corporation® that Revascor is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Advanced Heart Failure (must meet all)**:**^

^If member has an LVAD, please refer to criteria set I.B below.

1. Diagnosis of advanced HFrEF with all of the following characteristics (a-e):*
   a. High-risk defined as one of the following (i, ii, or iii):
      i. At least 1 heart failure hospitalization in the last 9 months;
      ii. At least 1 outpatient urgent care heart failure visit requiring intravenous diuretic, vasodilator, and/or positive inotropic therapy in the last 9 months;
      iii. Plasma levels of N-terminal pro–B-type natriuretic peptide (NT-proBNP) > 1,000 pg/mL (> 1,200 pg/mL for members with atrial fibrillation);
   b. Left ventricular ejection fraction (LVEF) ≤ 40% by 2-dimensional echocardiogram or ≤ 35% by multigated acquisition scan;
   c. New York Heart Association (NYHA) functional class II or III;
   d. Presence of ischemic cardiomyopathy;

e. Presence of inflammation as evidenced by baseline plasma high-sensitivity C-reactive protein (CRP) ≥ 2 mg/L;

2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;*
4. Member is receiving stable (i.e., no changes in dose for at least the last month), optimally tolerated dosages of guideline-directed medical therapies for HFrEF that includes all of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d; *see Appendix B*):*
   a. Beta-blocker;
   b. Angiotensin receptor/neprilysin inhibitor (ARNI), angiotensin-converting enzyme (ACE) inhibitor, or angiotensin-receptor blocker (ARB);
   c. Mineralocorticoid antagonist;
   d. Sodium-glucose cotransporter 2 (SGLT2) inhibitor;
5. Member has not previously received any stem cell therapy;*
6. Dose does not exceed a single transendocardial injection.*

Approval duration: 3 months (one transendocardial injection per lifetime)

B. End-Stage Heart Failure (must meet all)**:**

1. Diagnosis of end-stage chronic HFrEF with all of the following characteristics (a, b, and c):*
   a. LVEF ≤ 40% by 2-dimensional echocardiogram or ≤ 35% by multigated acquisition scan;
   b. NYHA functional class III or IV;
   c. Presence of ischemic cardiomyopathy;
2. Prescribed by or in consultation with a cardiologist;
3. Age ≥ 18 years;*
4. Member has an implanted LVAD, or is scheduled to receive an LVAD and will receive Revascor at the time of LVAD implantation;*
5. Member is receiving stable (i.e., no changes in dose for at least the last month), optimally tolerated dosages of guideline-directed medical therapies for HFrEF that includes all of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a, b, c, and d; *see Appendix B*):*
   a. Beta-blocker;
   b. ARNI, ACE inhibitor, or ARB;
   c. Mineralocorticoid antagonist;
   d. SGLT2 inhibitor;
6. Member has not previously received any stem cell therapy;*
7. Dose does not exceed a single transendocardial injection.*

Approval duration: 3 months (one transendocardial injection per lifetime)

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of

business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or

b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Heart Failure

1. Continued therapy will not be authorized as Revascor is indicated to be dosed one time only.*

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

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

A. 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.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACE: angiotensin-converting enzyme
ARB: angiotensin-receptor blocker
ARNI: angiotensin receptor/neprilysin inhibitor

CRP: C-reactive protein
FDA: Food and Drug Administration
HFrEF: heart failure with reduced ejection fraction
LVAD: left ventricular assist device
LVEF: left ventricular ejection fraction
NT-proBNP: N-terminal pro–B-type natriuretic peptide
NYHA: New York Heart Association
SGLT2: sodium-glucose cotransporter 2

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Beta blockers: bisoprolol, carvedilol, metoprolol	Varies	Varies
ARNI: Entresto® (sacubitril/valsartan)	24/26 to 49/51 mg PO BID	97/103 mg BID
ACE inhibitors: captopril, enalapril, lisinopril, ramipril	Varies	Varies
ARBs: candesartan, losartan, valsartan	Varies	Varies
Mineralocorticoid antagonists: eplerenone, spironolactone	Varies	Varies
SGLT2 inhibitors: dapagliflozin (Farxiga®), Jardiance® (empagliflozin), Inpefa® (sotagliflozin)	Varies	Varies

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 [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
HFrEF*	A single transendocardial injection*	Pending

VI. Product Availability [Pending]
Pending

VII. References
1. Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA guideline for the management of heart failure: A report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation. 2022; 145: e895-e1032.
2. Maddox TM, Januzzi JL, Allen LA, et al. 2024 ACC Expert Consensus Decision Pathway for treatment of heart failure with reduced ejection fraction: A report of the American College of Cardiology Solution Set Oversight Committee. JACC. 2024; 83(15): 1444-1488.

3. Perin EC, Borow KM, Henry TD, et al. Randomized trial of targeted transendocardial mesenchymal precursor cell therapy in patients with heart failure. JACC. 2023; 81(9): 849-873. doi:10.1016/j.jacc.2022.11.061
4. Perin EC, Borow KM, Henry TD, et al. Mesenchymal precursor cells reduce mortality and major morbidity in ischaemic heart failure with inflammation: DREAM-HF. European Journal of Heart Failure. 2024. doi:10.1002/ejhf.3522
5. ClinicalTrials.gov. Efficacy and safety of allogeneic mesenchymal precursor cells (rexlemestrocel-L) for the treatment of heart failure (DREAM HF-1). Available at: https://clinicaltrials.gov/study/NCT02032004. Accessed January 26, 2026.
6. Yau TM, Pagani FD, Mancini DM, et al. Intramyocardial injection of mesenchymal precursor cells and successful temporary weaning from left ventricular assist device support in patients with advanced heart failure: A randomized clinical trial. JAMA. 2019; 321(12): 1176-1186. doi:10.1001/jama.2019.2341
7. ClinicalTrials.gov. Safety & efficacy of intramyocardial injection of mesenchymal precursor cells on myocardial function in LVAD recipients. Available at: https://clinicaltrials.gov/study/NCT02362646. Accessed January 26, 2026.

Coding Implications [Pending]
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Pending	Pending

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	04.08.25	05.25
2Q 2026 annual review: no significant changes as the drug is not yet FDA-approved; updated language under Policy/Criteria to effectively redirect prior authorization reviews to Precision Drug Action Committee (PDAC) Utilization Management Review; references reviewed and updated. Added ICHRA line of business.	03.30.26	05.26

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.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members, and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.