Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy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: Autologous Cutaneous Multicellular Units (SkinTE)

Reference Number: CP.PHAR.814
Effective Date: FDA Approval Date
Last Review Date: 11.26
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.

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Description

Autologous cutaneous multicellular units (SkinTE®) is an autologous cutaneous multicellular therapy.

FDA Approved Indication(s) [Pending]

SkinTE is indicated for the treatment of Wagner Grade 1 diabetic foot ulcers (DFU).

Limitation(s) of use: [XXX]

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 SkinTE 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. Diabetic Foot Ulcers (must meet all)**:**

1. Diagnosis of type 1 or type 2 diabetes mellitus with Wagner Grade 1 DFU (*see Appendix D)*;*
2. Prescribed by or in consultation with a podiatrist, wound care specialist, or general or vascular surgeon;
3. Age ≥ 18 years;*
4. Ulcer site meets all of the following (a, b, and c):
   a. Size > 1 cm^2 and < 25 cm^2;*
   b. Present for at least 4 weeks;*
   c. Has not previously been treated with SkinTE;
5. Documentation of adequate circulation in affected foot (within the last 3 months), evidenced by one of the following (a, b, or c):*
   a. Transcutaneous oxygen measurement or a skin perfusion pressure measurement of ≥ 30 mmHg;

b. Ankle-brachial index of ≥ 0.7 and ≤ 1.2;
c. Arterial doppler ultrasound with a minimum of biphasic flow;

6. Documentation of recent (within the last 3 months) HbA1c < 12%;*
7. Provider attestation that member is concomitantly receiving standard of care preventative or treatment therapies for ulcer wound care (e.g., regular debridement, appropriate wound dressings, pressure offloading [e.g., total contact cast, removable cast walker]); *
8. At time of request, member does not have ulcer suspected of cancer, active osteomyelitis, cellulitis, soft tissue infection, or active Charcot's arthropathy present on the affected foot or limb involving the ulcer;*
9. Dose does not exceed a one-time surgical application per wound.*

Approval duration: 3 months (*1 surgical application per wound*)

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.

II. Continued Therapy*

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

A. Diabetic Foot Ulcers:

1. Reauthorization is not permitted. Members must meet the initial approval criteria if request is for previously untreated or newly developed ulcers.

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

INTERNAL POLICY AND INFORMATION - SUBJECT TO CHANGE

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
DFU: diabetic foot ulcers
FDA: Food and Drug Administration
HbA1c: glycated hemoglobin

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings [Pending]
- Contraindication(s): pending
- Boxed warning(s): pending

Appendix D: General Information
- The Wagner DFU classification system:
  - Grade 1: superficial ulcer (on the outer layers of skin)
  - Grade 2: deeper, full thickness extension (deep ulcer)
  - Grade 3: deep abscess formation or osteomyelitis (ulcer with bone involvement)
  - Grade 4: partial gangrene of forefoot
  - Grade 5: extensive gangrene

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
DFU*	Pending*	Pending*

VI. Product Availability [Pending]
Pending

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VII. References

1. Armstrong DG, Orgill DP, Galiano R, et al. A multicenter, randomized controlled clinical trial evaluating the effects of novel autologous heterogeneous skin construct in the treatment of Wagner one diabetic foot ulcers: Final analysis. Int Would J. 2023;20:4083-4096.
2. Clinicaltrials.gov. SkinTE for the treatment of Wagner 1 diabetic foot ulcers (COVER DFUSII). Available at: https://clinicaltrials.gov/study/NCT06140303. Accessed October 6, 2026.
3. Schaper N, vann Netten JJ, Apelqvist J, et al. Practical guidelines on the prevention and management of diabetes-related foot disease. Diabetes/Metabolism Research and Reviews. 2024;40(3):e3657.

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	10.20.26	11.26

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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.

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