Clinical Policy: Non-Formulary Test Strips

Reference Number: HIM.PA.34
Effective Date: 02.01.16
Last Review Date: 02.26
Line of Business: HIM

Revision Log

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

Description
Blood glucose test strips are used with blood glucose meters to monitor blood glucose levels. Prior authorization is required for non-formulary blood glucose test strips.

FDA Approved Indication(s)
Blood glucose test strips are indicated for use in patients with diabetes mellitus to monitor blood glucose levels.

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 non-formulary blood glucose test strips are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Request for Non-Formulary Test Strips:

1. Provider submits a letter of medical necessity detailing why current formulary products cannot be used (e.g., dexterity impairment, use of an insulin pump requiring specific test strips).

Approval duration: 12 months

B. Other diagnoses/indications: Not applicable

II. Continued Therapy

A. Request for Non-Formulary Test Strips:

1. Member meets one of the following (a or b):
   a. Currently receiving prescribed product via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving prescribed product and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B).*

Approval duration: 12 months

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
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Usage regimen is individualized based on patient-specific goals.

VI. Product Availability

Test strip packaging varies by product and manufacturer.

VII. References

Not applicable

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2022 annual review: no significant changes; references reviewed and updated.	09.16.21	02.22
Template changes applied to continued therapy section.	10.11.22	
1Q 2023 annual review: no significant changes; references reviewed and updated.	10.27.22	02.23
1Q 2024 annual review: no significant changes; references reviewed and updated.	10.19.23	02.24
1Q 2025 annual review: no significant changes; references reviewed and updated.	11.05.24	02.25
1Q 2026 annual review: no significant changes; references reviewed and updated.	11.13.25	02.26

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.