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Clinical Policy: Quantity Limit of Diabetic Test Strips for Members Not Receiving Insulin

Reference Number: CP.PPA.25

Effective Date: 09/01/2017

Last Review Date: 08/17

Line of Business: Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Diabetic test strips are used with glucometers to monitor blood glucose levels. Prior authorization is required for members not receiving concurrent insulin therapy who have exceeded a quantity limit of 100 test strips within a 90-day period.

FDA Approved Indication(s)

Diabetic test strips are indicated for use in patients with diabetes mellitus to monitor blood glucose levels.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation[®] that diabetic test strips are **medically necessary** for members not receiving concurrent insulin therapy when the following criteria are met:

I. Initial Approval Criteria

***These criteria do not apply to members on insulin. If member is determined to be on insulin (e.g., chart notes), approve per health plan quantity limit. ***

A. Test Strip Use in Excess of 100 Strips/90 Days or In Excess of State-Requirements (must meet all):

1. Diagnosis of diabetes mellitus;
2. Prescribed for self-monitoring of blood glucose (SMBG);
3. Provider submits a letter of medical necessity detailing all of the following (a-c):
 - a. Number of test strips required daily;
 - b. Reason for rigorous (greater than once daily) SMBG in the absence of insulin therapy (*see Appendix C for examples*) and how this will lead to improved member health outcomes;
 - c. Expected duration of rigorous monitoring.

Approval duration: Duration of request or 6 months (whichever is less)

**Approve the quantity requested by the provider or up to a maximum of 10 strips/day (whichever is less)*

B. Other diagnoses/indications: Not applicable

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***These criteria do not apply to members on insulin. If member is determined to be on insulin (e.g., chart notes), approve per health plan quantity limit. ***

A. Test Strip Use in Excess of 100 Strips/90 Days or In Excess of State-Requirements
(must meet all):

1. Previously authorized to receive > 100 test strips in a 90-day period via Centene benefit or member has previously met the initial approval criteria;
2. Provider submits a letter of medical necessity detailing why the member must continue to perform rigorous SMBG in the absence of insulin therapy (*see Appendix C for examples*) with the following details (a and b):
 - a. Number of test strips required daily;
 - b. Expected duration of rigorous monitoring.

Approval duration: Duration of request or 6 months (whichever is less)

**Approve the quantity requested by the provider or up to a maximum of 10 strips/day (whichever is less)*

B. Other diagnoses/indications: Not applicable**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 policy – CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

SMBG: self-monitoring of blood glucose

Appendix B: Self-Monitoring of Blood Glucose

- SMBG is a tool used to evaluate whether glycemic targets are being achieved. SMBG enables evaluation of response to both pharmacologic therapy and lifestyle modifications and can therefore help guide treatment decisions and/or self-management.
- Per both the American Diabetes Association and American Association of Clinical Endocrinologists/American College of Endocrinology 2017 guidelines, SMBG should be performed by all patients receiving insulin therapy. Patients who are not receiving insulin therapy can also benefit from SMBG, although there is no clear guidance on when SMBG should be initiated or how frequently it should be performed. Instead, it depends on individual patient needs and goals.

Appendix C: Examples of Reasons for Rigorous Self-Monitoring of Blood Glucose

Examples of cases necessitating rigorous SMBG include, but are not limited to, cystic fibrosis-related diabetes and severe glucose abnormalities during pregnancy.

V. Dosage and Administration

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Usage regimen is individualized based on patient’s goals.

VI. Product Availability

Test strip packaging varies by product and manufacturer.

VII. References

1. American Diabetes Association. Standards of medical care in diabetes—2017. *Diabetes Care*. 2017; 40(suppl 1): S1-S135.
2. Garber AJ, Abrahamson MJ, Barzilay, JI, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm – 2017 executive summary. *Endocr Pract*. 2017; 23(2): 207-238.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	08.16.17	08/17

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.

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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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