

Clinical Policy: Blood Glucose Test Strip Quantity Limit - Not Receiving Insulin

Reference Number: CP.PMN.151

Effective Date: 09.01.17 Last Review Date: 02.21 Line of Business: Medicaid

Revision Log

See <u>Important Reminder</u> 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 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)

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 blood glucose test strips in excess of 100 strips per 90 days or in excess of state requirements are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

- A. Test Strips 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 E* 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 per day (whichever is less).

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B. Other diagnoses/indications: Not applicable

II. Continued Therapy

These criteria do not apply to members on insulin. If the 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 E* for examples) detailing both of the following (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 per day (whichever is less).

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 SMBG: self-monitoring of blood glucose

Appendix B: Therapeutic Alternatives Not applicable

Appendix C: Contraindications/Boxed Warnings None reported

Appendix D: General Information

- 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, 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 E: Self-Monitoring of Blood Glucose: Examples for Rigorous Testing

- Cystic fibrosis-related diabetes
- Severe glucose abnormalities during pregnancy

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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

- 1. American Diabetes Association. Standards of medical care in diabetes—2020. Diabetes Care. 2020; 43(suppl 1): S1-S212. Updated June 5, 2020. Accessed October 26, 2020.
- 2. Garber AJ, Handelsman Y, Grunberger G, et al. Consensus statement by the American Association of Clinical Endocrinologists and American College of Endocrinology on the comprehensive type 2 diabetes management algorithm 2020 executive summary. Endocr Pract. 2020; 26(1): 107-139.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	08.16.17	08.17
3Q 2018 annual review: Changed from CP.PPA.25 QL of Diabetic Test Strips not receiving insulin; references reviewed and updated.	06.15.18	08.18
1Q 2019 annual review: no significant changes; modified "diabetic test strips" to "blood glucose test strips"; references reviewed and updated.	10.12.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	09.25.19	02.20
1Q 2021 annual review: no significant changes; references reviewed and updated.	10.26.20	02.21

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

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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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