

Clinical Policy Title:	Blood glucose test strip quantity limit - Not Receiving Insulin
Policy Number:	RxA.097
Drug(s) Applied:	Blood glucose test strips
Original Policy Date:	02/07/2020
Last Review Date:	01/17/2022
Line of Business Policy Applies to:	All lines of business

Background

Blood glucose 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.

Blood glucose test strips are indicated for use in patients with diabetes mellitus to monitor blood glucose levels. Usage regimen is individualized based on patient's goals. Test strip packaging varies by product and manufacturer.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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

Commercial: 6 months

Medicaid: 6 months

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

II. Continued Therapy Approval

****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):

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

1. Member is previously authorized to receive > 100 test strips in a 90-day period via RxAdvance 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) with the following details (a and b):
 - a. Number of test strips required daily;
 - b. Expected duration of rigorous monitoring.

Approval duration

Commercial: 6 months

Medicaid: 6 months

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

III. Appendices

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

- Contraindication(s):
 - None reported.
- Boxed Warning(s):
 - 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 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 E: Self-Monitoring of Blood Glucose: Examples for Rigorous Testing

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

References

1. American Diabetes Association. Standards of medical care in diabetes - 2018. Diabetes Care. 2020. Available at: https://care.diabetesjournals.org/content/diacare/41/Supplement_1/S105.full.pdf. Accessed on December 6, 2021.
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. Available at:
[https://www.endocrinepractice.org/article/S1530-891X\(20\)35557-9/fulltext](https://www.endocrinepractice.org/article/S1530-891X(20)35557-9/fulltext). Accessed December 6 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Policy was reviewed: <ol style="list-style-type: none"> 1. Clinical policy title was updated. 2. Line of business policy applies to was updated to all lines of business. 3. Commercial and Medicaid approval duration was added in Initial and continued therapy approval criteria. 4. Updated Appendix C 5. References were reviewed and updated. 	02/09/2021	03/09/2021
Policy was reviewed: <ol style="list-style-type: none"> 1. Statement about provider sample “The provision of provider samples does not guarantee coverage...” was added to Clinical Policy. 2. References were reviewed and updated. 	12/06/2021	01/17/2022